

Stability Report # 183G03
SU010398 expiring

ACCO. USA
WHEELING, ILLINOIS 60090

15044



0505 15044 1
BEN/VERT FEUILLE/VERDE SUAVE

Submission Id: 116305

Sample ID (Request No.): 20021134

User sample ID (lot): 183G03

Sample Type: SU010398 (PNU290940AD) CAPSULE
25MG

Request Type: STABILITY

Stability Study: 183G03

Pack Type: 30 ml PLASTIC BOTTLE

Storage Condition: 25°C/60% U.R.

Time Label: 6 MONTHS

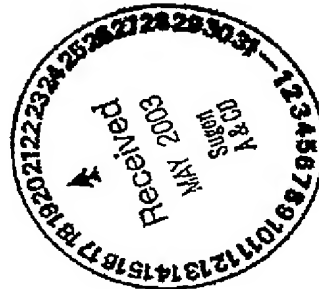
Preparation purpose: CLINICAL SUPPLY + STABILITY

Condition :
APPROVED

Status :
COMPLETE

Samples Notes:

Method	Controls	Results	Vers.	M.U.	Spec?	Lower lim	Upper lim	Book-Data Analyses	Analyst	Verifier
083GCO02#00	CAPSULE APPEARANCE	0=UNCHANGED	1	bt				15545/18- MAY 2002	CAPPUCCIO	MARIANI
	CAPSULE COLOR	0=UNCHANGED	1	bt				15545/18- MAY 2002	CAPPUCCIO	MARIANI
	CONTENT APPEARANCE	0=UNCHANGED	1	bt				15545/18- MAY 2002	CAPPUCCIO	MARIANI
	CONTENT COLOR	0=UNCHANGED	1	bt				15545/18- MAY 2002	CAPPUCCIO	MARIANI
	SMELL	0=UNCHANGED	1	bt				15545/18- MAY 2002	CAPPUCCIO	MARIANI
083GT01#01_S	(HPLC TITER) SAMPLE#1	97.95	1	%		90.000	- 110.000	15545/18- MAY 2002	CAPPUCCIO	MARIANI
	(HPLC TITER) SAMPLE#2	97.96	1	%		90.000	- 110.000	15545/18- MAY 2002	CAPPUCCIO	MARIANI
	(HPLC TITER) SAMPLE#3	97.25	1	%		90.000	- 110.000	15545/18- MAY 2002	CAPPUCCIO	MARIANI
	AVERAGE TITER (HPLC)	97.72	1	%		90.000	- 110.000	15545/18- MAY 2002	CAPPUCCIO	MARIANI
083GSC01#00	TOTAL CORRELATED SUBSTANCES	0.18	1	%				15545/18- MAY 2002	CAPPUCCIO	MARIANI
	IMPURITIES NOT LESS THAN 0.05%	SEE TEXT	1	%				15545/18- MAY 2002	CAPPUCCIO	MARIANI
083GKF01#00	(HUMIDITY) SAMPLE #1	2.37	1	%				15545/18- MAY 2002	CAPPUCCIO	MARIANI
	(HUMIDITY) SAMPLE #2	2.4	1	%				15545/18- MAY 2002	CAPPUCCIO	MARIANI
	(HUMIDITY) SAMPLE #3	2.38	1	%				15545/18- MAY 2002	CAPPUCCIO	MARIANI
	AVERAGE HUMIDITY	2.38	1	%				15545/18- MAY 2002	CAPPUCCIO	MARIANI



Submission Id: 116305
Sample ID (Request No.): 20021134
User sample ID (lot): **183G03**

Sample Type: SU010398 (PNU280940AD) -- CAPSULE
25MG

Request Type: STABILITY
Stability Study: 183G03
Pack Type: 30 ml PLASTIC BOTTLE
Storage Condition: 25°C/60% U.R.
Time Label: 6 MONTHS
Preparation purpose: CLINICAL SUPPLY + STABILITY

Condition :
APPROVED
Status :
COMPLETE

Samples Notes:

Method	Controls	Results	Vers.	M.U.	Spec?	Lower lim	Upper lim	Book-Data Analyses	Analyst	Verifier
083GDS01#01	SAMPLE#1	94.01	1	%		80.000		15545/18- MAY 2002	CAPPUCCIO	MARIANI
	SAMPLE#2	99.04	1	%		80.000		15545/18- MAY 2002	CAPPUCCIO	MARIANI
	SAMPLE#3	100.16	1	%		80.000		15545/18- MAY 2002	CAPPUCCIO	MARIANI
	SAMPLE#4	94.01	1	%		80.000		15545/18- MAY 2002	CAPPUCCIO	MARIANI
	SAMPLE#5	88.41	1	%		80.000		15545/18- MAY 2002	CAPPUCCIO	MARIANI
	SAMPLE#6	94.58	1	%		80.000		15545/18- MAY 2002	CAPPUCCIO	MARIANI
	DISSOLUTION	95.03	1	%		80.000		15545/18- MAY 2002	CAPPUCCIO	MARIANI
	STANDARD DEVIATION	4.208	1	std-1				15545/18- MAY 2002	CAPPUCCIO	MARIANI
	C.V.	4.43	1	%				15545/18- MAY 2002	CAPPUCCIO	MARIANI
	MIN. DISSOLUTION VALUE	88.41	1	%		80.000		15545/18- MAY 2002	CAPPUCCIO	MARIANI
	MAX. DISSOLUTION VALUE	100.16	1	%		80.000		15545/18- MAY 2002	CAPPUCCIO	MARIANI

PHARMACIA

Global Pharmaceutical Sciences - Italy

Analyses Report

Laboratory
Information
Management
System

Submission Id: 116305

Sample ID (Request No.) : 20021134

User sample ID (lot) : 183G03

Sample Type: SU010398 (PNU280840AD) CAPSULE
25MG

Request Type: STABILITY

Stability Study: 183G03

Pack Type: 30 ml PLASTIC BOTTLE

Storage Condition: 25°C/60% U.R.

Time Label: 6 MONTHS

Preparation purpose: CLINICAL SUPPLY + STABILITY

Condition :
APPROVED

Status :
COMPLETE

Samples Notes:

Observations on the Method 083GC02#00, component: CAPSULE APPEARANCE

Opaque brick red colored, format 3, hard gelatin capsule containing yellow-orange powder

Observations on the Method 083GDS01#01, component: DISSOLUTION

Dissolution at 15 minutes: 76.5% (C.V.=13.9%)

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Analyses Report

Laboratory
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Submission Id: 116305

Sample ID (Request No.): 20021134

User sample ID (lot): 183G03

Sample Type: SU010398 (PNU280840AD) CAPSULE
25MG

Request Type: STABILITY

Stability Study: 183G03

Pack Type: 30 ml PLASTIC BOTTLE

Storage Condition: 25°C/60% U.R.

Time Label: 6 MONTHS

Preparation purpose: CLINICAL SUPPLY + STABILITY

Condition :
APPROVED

Status :
COMPLETE

Samples Notes:

Observations on the Method 083GDS01#01, component: DISSOLUTION

Dissolution at 45 minutes: 99.97% (C.V.=1.16%)

Observations on the Method 083GSC01#00, component: IMPURITIES NOT LESS than 0.05%

Total correlated substances: 0.18%



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Analyses Report

Laboratory
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Submission Id: 116305

Sample ID (Request No.): 20021134

User sample ID (lot): **183G03**

Sample Type: SU010398 (PNU230940AD) CAPSULE
25MG

Request Type: STABILITY

Stability Study: 183G03

Pack Type: 30 ml PLASTIC BOTTLE

Storage Condition: 25°C/60% U.R.

Time Label: 6 MONTHS

Preparation purpose: CLINICAL SUPPLY + STABILITY

Condition :
APPROVED

Status :
COMPLETE

Samples Notes:

Observations on the Method 083GSC01400, component: IMPURITIES NOT LESS THAN 0.05%

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Analyses Report

Laboratory
Information
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System

Submission Id: 116305
Sample ID (Request No.): 20021134
User sample ID (lot): **I83G03**

Sample Type: SU010398 (PNU290940AD) CAPSULE
25MG

Request Type: STABILITY
Stability Study: I83G03

Pack Type: 30 ml PLASTIC BOTTLE

Storage Condition: 25°C/60% U.R.

Time Label: 6 MONTHS

Preparation purpose: CLINICAL SUPPLY + STABILITY

Condition :
APPROVED

Status :
COMPLETE

Samples Notes:

Observations on the Method 083GSC01#00, component: IMPURITIES NOT LESS THAN 0.05%

RRT Area (%)

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Analyses Report

Laboratory
Information
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System

Submission Id: 116305
Sample ID (Request No.): 20021134
User sample ID (lot): **183G03**
Sample Type: SU010398 (PNU290940AD) CAPSULE
25MG

Request Type: STABILITY
Stability Study: 183G03
Pack Type: 30 ml PLASTIC BOTTLE
Storage Condition: 25°C/60% U.R.
Time Label: 6 MONTHS
Preparation purpose: CLINICAL SUPPLY + STABILITY

Condition :
APPROVED
Status :
COMPLETE

Samples Notes:

Observations on the Method 083GSC01H00, component: IMPURITIES NOT LESS THAN 0.05%



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Analyses Report

Laboratory
Information
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Submission Id: 116305

Sample ID (Request No.): 20021134

User sample ID (lot): I83G03

Sample Type: SU010398 (PNU290940AD) CAPSULE
25MG

Request Type: STABILITY

Stability Study: I83G03

Pack Type: 30 ml PLASTIC BOTTLE

Storage Condition: 25°C/60% U.R.

Time Label: 6 MONTHS

Preparation purpose: CLINICAL SUPPLY + STABILITY

Condition :
APPROVED

Status :
COMPLETE

Samples Notes:

Observations on the Method

083GSC01#00, component: IMPURITIES NOT LESS THAN 0.05%

0.66 0.12



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Analyses Report

Laboratory
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Submission Id: 116305	Request Type: STABILITY	Condition : APPROVED
Sample ID (Request No.): 20021134	Stability Study: I83G03	Status : COMPLETE
User sample ID (lot): I83G03	Pack Type: 30 ml PLASTIC BOTTLE	
Sample Type: SU010398 (PNU280940AD) CAPSULE	Storage Condition: 25°C/60% U.R.	
	Time Label: 6 MONTHS	
	Preparation purpose: CLINICAL SUPPLY + STABILITY	

Samples Notes:

Observations on the Method 083GSC01#00, component: IMPURITIES NOT LESS THAN 0.05%

0.91 0.08

Analyses Report

Submission Id: 116305

Sample ID (Request No.): 20021134

User sample ID (lot): 183G03

Sample Type: SU010398 (PNU290940AD) CAPSULE
25MG

Request Type: STABILITY

Stability Study: 183G03

Pack Type: 30 ml PLASTIC BOTTLE

Storage Condition: 25°C/60% U.R.

Time Label: 6 MONTHS

Preparation purpose: CLINICAL SUPPLY + STABILITY

Condition :
APPROVED

Status :
COMPLETE

Samples Notes:

Observations on the Method 083GSC01#00, component: IMPURITIES NOT LESS THAN 0.05%

1.00 99.82 (SU11248)

SUBMISSION APPROVED BY Volker ECK
APPROVE DATE 15-may-2003

SAMPLE APPROVED BY: ROSARIA MARIANI
APPROVE DATE: 17-may-2002

Submission Id: 116307
Sample ID (Request No.): 20021136
User sample ID (lot): 183G03

Sample Type: SU010398 (PNU290940AD) CAPSULE
25MG

Request Type: STABILITY
Stability Study: 183G03

Pack Type: 30 ml PLASTIC BOTTLE
Storage Condition: 40°C/75% U.R.

Time Label: 6 MONTHS

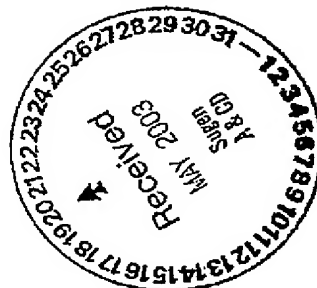
Preparation purpose: CLINICAL SUPPLY + STABILITY

Condition: **APPROVED**

Status: **COMPLETE**

Samples Notes:

Method	Controls	Results	Vers.	M.U.	Spec?	Lower lim	Upper lim	Book-Data Analyses	Analyst	Verifier
083GCO02#00	CAPSULE APPEARANCE	0=UNCHANGED	1	bd				15545/18- MAY 2002	CAPPUCCIO	MARIANI
	CAPSULE COLOR	0=UNCHANGED	1	bd				15545/18- MAY 2002	CAPPUCCIO	MARIANI
	CONTENT APPEARANCE	0=UNCHANGED	1	bd				15545/18- MAY 2002	CAPPUCCIO	MARIANI
	CONTENT COLOR	0=UNCHANGED	1	bd				15545/18- MAY 2002	CAPPUCCIO	MARIANI
	SMELL	0=UNCHANGED	1	bd				15545/18- MAY 2002	CAPPUCCIO	MARIANI
083GT01#01_S	(HPLC TITER) SAMPLE#1	97.43	1	%		90.000	110.000	15545/18- MAY 2002	CAPPUCCIO	MARIANI
	(HPLC TITER) SAMPLE#2	98.55	1	%		90.000	110.000	15545/18- MAY 2002	CAPPUCCIO	MARIANI
	(HPLC TITER) SAMPLE#3	97.23	1	%		90.000	110.000	15545/18- MAY 2002	CAPPUCCIO	MARIANI
	AVERAGE TITER (HPLC)	97.74	1	%		90.000	110.000	15545/18- MAY 2002	CAPPUCCIO	MARIANI
	TOTAL CORRELATED SUBSTANCES	0.21	1	%				15545/18- MAY 2002	CAPPUCCIO	MARIANI
083GSC01#00	IMPURITIES NOT LESS THAN 0.05%	SEE TEXT	1	%				15545/18- MAY 2002	CAPPUCCIO	MARIANI
	(HUMIDITY) SAMPLE #1	2.77	1	%				15545/18- MAY 2002	CAPPUCCIO	MARIANI
	(HUMIDITY) SAMPLE #2	2.9	1	%				15545/18- MAY 2002	CAPPUCCIO	MARIANI
	(HUMIDITY) SAMPLE #3	2.8	1	%				15545/18- MAY 2002	CAPPUCCIO	MARIANI
	AVERAGE HUMIDITY	2.82	1	%				15545/18- MAY 2002	CAPPUCCIO	MARIANI



Submission Id: 116307
Sample ID (Request No.): 20021136
User sample ID (lot): 183G03

Sample Type: SU010398 (PNU290940AD) CAPSULE
25MG

Request Type: STABILITY
Stability Study: I83G03

Pack Type: 30 ml PLASTIC BOTTLE

Storage Condition: 40°C/75% U.R.

Time Label: 6 MONTHS

Preparation purpose: CLINICAL SUPPLY + STABILITY

Condition: **APPROVED**

Status: **COMPLETE**

Samples Notes:

Method	Controls	Results	Vers.	M.U.	Spec?	Lower lim	Upper lim	Book-Data Analyses	Analyst	Venier
083GDS01#01	SAMPLE#1	96.29	1	%		80.000		15545/18- MAY 2002	CAPPUCCIO	MARIANI
	SAMPLE#2	95.75	1	%		80.000		15545/18- MAY 2002	CAPPUCCIO	MARIANI
	SAMPLE#3	95.82	1	%		80.000		15545/18- MAY 2002	CAPPUCCIO	MARIANI
	SAMPLE#4	100.05	1	%		80.000		15545/18- MAY 2002	CAPPUCCIO	MARIANI
	SAMPLE#5	99.51	1	%		80.000		15545/18- MAY 2002	CAPPUCCIO	MARIANI
	SAMPLE#6	97.90	1	%		80.000		15545/18- MAY 2002	CAPPUCCIO	MARIANI
	DISSOLUTION	97.72	1	%		80.000		15545/18- MAY 2002	CAPPUCCIO	MARIANI
	STANDARD DEVIATION	1.755	1	std-1				15545/18- MAY 2002	CAPPUCCIO	MARIANI
	C.V.	1.8	1	%				15545/18- MAY 2002	CAPPUCCIO	MARIANI
	MIN. DISSOLUTION VALUE	95.75	1	%		80.000		15545/18- MAY 2002	CAPPUCCIO	MARIANI
	MAX. DISSOLUTION VALUE	100.05	1	%		80.000		15545/18- MAY 2002	CAPPUCCIO	MARIANI

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Analyses Report

Laboratory
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Submission Id: 116307

Sample ID (Request No.) : 20021136

User sample ID (lot) : I83G03

Sample Type: SU010398 (PNU290940AD) CAPSULE
25MG

Request Type: STABILITY

Stability Study: I83G03

Pack Type: 30 ml PLASTIC BOTTLE

Storage Condition: 40°C/75% U.R.

Time Label: 6 MONTHS

Preparation purpose: CLINICAL SUPPLY + STABILITY

Condition :
APPROVED

Status :
COMPLETE

Samples Notes:

Observations on the Method 083GCC02#00, component: CAPSULE APPEARANCE

Opaque brick red colored, format 3, hard gelatin capsule containing yellow-orange powder

Observations on the Method 083GDS01#01, component: DISSOLUTION

Dissolution at 15 minutes: 96.74% (C.V. = 1.77%)

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Analyses Report

Laboratory
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Submission Id: 116307
Sample ID (Request No.): 20021136
User sample ID (lot): **I83G03**
Sample Type: SU010398 (PNU280840AD) CAPSULE
25MG

Request Type: STABILITY
Stability Study: I83G03
Pack Type: 30 ml PLASTIC BOTTLE
Storage Condition: 40°C/75% U.R.
Time Label: 6 MONTHS
Preparation purpose: CLINICAL SUPPLY + STABILITY

Condition :
APPROVED
Status :
COMPLETE

Samples Notes:

Observations on the Method 083GDS01#01, component: DISSOLUTION

Dissolution at 45 minutes: 97.72% (C.V.: 1.86%)

Observations on the Method 083GSC01#00, component: IMPURITIES NOT LESS THAN 0.05%

Total correlated substances: 0.21%

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Analyses Report

Laboratory
Information
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Submission Id: 116307
Sample ID (Request No.): 20021136
User sample ID (lot): **183G03**
Sample Type: SU010398 (PNU290940AD) CAPSULE
25MG

Request Type: STABILITY
Stability Study: 183G03
Pack Type: 30 ml PLASTIC BOTTLE
Storage Condition: 40°C/75% U.R.
Time Label: 6 MONTHS
Preparation purpose: CLINICAL SUPPLY + STABILITY

Condition :
APPROVED
Status :
COMPLETE

Samples Notes:

Observations on the Method 083GSC01#00, component: IMPURITIES NOT LESS THAN 0.05%



Submission Id: 116307

Sample ID (Request No.): 20021138

User sample ID (lot): 183G03

Sample Type: SU010388 (PNU290840AD) CAPSULE
25MG

Request Type: STABILITY

Stability Study: 183G03

Pack Type: 30 ml PLASTIC BOTTLE

Storage Condition: 40°C/75% U.R.

Time Label: 6 MONTHS

Preparation purpose: CLINICAL SUPPLY + STABILITY

Condition :
APPROVED

Status :
COMPLETE

Samples Notes:

Observations on the Method 083GSC01#00, component: IMPURITIES NOT LESS THAN 0.05%

RRT Area (%)

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Analyses Report

Laboratory
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Submission Id: 116307
Sample ID (Request No.): 20021136
User sample ID (lot): **I83G03**
Sample Type: SU010398 (PNU290940AD) CAPSULE
25MG

Request Type: STABILITY
Stability Study: I83G03
Pack Type: 30 ml PLASTIC BOTTLE
Storage Condition: 40°C/75% U.R.
Time Label: 6 MONTHS
Preparation purpose: CLINICAL SUPPLY + STABILITY

Condition :
APPROVED
Status :
COMPLETE

Samples Notes:

Observations on the Method 083GSC01#00, component IMPURITIES NOT LESS THAN 0.05%

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Analyses Report

Laboratory
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Submission Id: 115307

Sample ID (Request No.): 20021136

User sample ID (lot): 183G03

Sample Type: SU010398 (PNU280940AD) CAPSULE
25MG

Request Type: STABILITY

Stability Study: 183G03

Pack Type: 30 ml PLASTIC BOTTLE

Storage Condition: 40°C/75% U.R.

Time Label: 6 MONTHS

Preparation purpose: CLINICAL SUPPLY + STABILITY

Condition:

APPROVED

Status:

COMPLETE

Samples Notes:

Observations on the Method

083GGC01#00, component: IMPURITIES NOT LESS THAN 0.05%

0.86

0.08

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Global Pharmaceutical Sciences - Italy

Analyses Report

Laboratory
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Submission Id: 116307

Sample ID (Request No.): 20021136

User sample ID (lot): 183G03

Sample Type: SU010398 (PNU290940AD) CAPSULE
25MG

Request Type: STABILITY

Stability Study: 183G03

Pack Type: 30 ml PLASTIC BOTTLE

Storage Condition: 40°C/75% U.R.

Time Label: 6 MONTHS

Preparation purpose: CLINICAL SUPPLY + STABILITY

Condition :
APPROVED

Status :
COMPLETE

Samples Notes:

Observations on the Method

083GSC01#00, component: IMPURITIES NOT LESS THAN 0.05%

0.91 0.06



Analyses Report

Submission Id: 116307
Sample ID (Request No.): 20021136
User sample ID (lot): **I83G03**
Sample Type: SU010398 (PNU290940AD) CAPSULE
25MG

Request Type: STABILITY
Stability Study: I83G03
Pack Type: 30 ml PLASTIC BOTTLE
Storage Condition: 40°C/75% U.R.
Time Label: 6 MONTHS
Preparation purpose: CLINICAL SUPPLY + STABILITY

Condition :
APPROVED
Status :
COMPLETE

Samples Notes:

Observations on the Method 083GSC01#00, component: IMPURITIES NOT LESS THAN 0.05%

0.94 0.07



Analyses Report

Laboratory
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Submission Id: 116307	Request Type: STABILITY	Condition : APPROVED
Sample ID (Request No.): 20021136	Stability Study: I83G03	Status : COMPLETE
User sample ID (lot): I83G03	Pack Type: 30 ml PLASTIC BOTTLE	
Sample Type: SU010398 (PNU290940AD) CAPSULE	Storage Condition: 40°C/75% U.R.	
25MG	Time Label: 6 MONTHS	
	Preparation, purpose: CLINICAL SUPPLY + STABILITY	

Samples Notes:

Observations on the Method 083GSC01#00, component: IMPURITIES NOT LESS THAN 0.05%

1.00 99.79 (SU11248)

SUBMISSION APPROVED BY Volker ECK
APPROVE DATE 15-may-2003

SAMPLE APPROVED BY: ROSARIA MARIANI
APPROVE DATE: 17-may-2002



Analyses Report

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Submission Id: 116953
Sample ID (Request No.): 20022083
User sample ID (lot): 183G03
Sample Type: SU010398 (PNU290940AD) CAPSULE
25MG

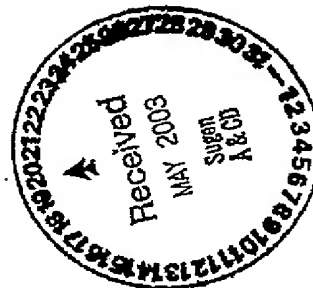
Request Type: STABILITY
Stability Study: 183G03
Pack Type: 30 ml PLASTIC BOTTLE
Storage Condition: 25°C/60% U.R.
Time Label: 9 MONTHS

Condition :
APPROVED
Status :
COMPLETE

Preparation purpose: CLINICAL SUPPLY + STABILITY

Samples Notes:

Method	Controls	Results	Vers.	M.U.	Spec?	Lower lim	Upper lim	Book-Data Analyses	Analyst	Verifier
083GCO02#00	CAPSULE APPEARANCE	0=UNCHANGED	1	bt				15545/33 AUG2002	CAPPUCCIO	FINETTI
	CAPSULE COLOR	0=UNCHANGED	1	bt				15545/33 AUG2002	CAPPUCCIO	FINETTI
	CONTENT APPEARANCE	0=UNCHANGED	1	bt				15545/33 AUG2002	CAPPUCCIO	FINETTI
	CONTENT COLOR	0=UNCHANGED	1	bt				15545/33 AUG2002	CAPPUCCIO	FINETTI
	SMELL	0=UNCHANGED	1	bt				15545/33 AUG2002	CAPPUCCIO	FINETTI
083GT01#01_S	(HPLC TITER) SAMPLE#1	97.48	1	%		90.000	- 110.000	15545/33 AUG2002	CAPPUCCIO	FINETTI
	(HPLC TITER) SAMPLE#2	96.12	1	%		90.000	- 110.000	15545/33 AUG2002	CAPPUCCIO	FINETTI
	(HPLC TITER) SAMPLE#3	97.03	1	%		90.000	- 110.000	15545/33 AUG2002	CAPPUCCIO	FINETTI
	AVERAGE TITER (HPLC)	96.88	1	%		90.000	- 110.000	15545/33 AUG2002	CAPPUCCIO	FINETTI
	TOTAL CORRELATED SUBSTANCES	0.32	1	%				15545/33 AUG2002	CAPPUCCIO	FINETTI
083GSC01#00	IMPURITIES NOT LESS THAN 0.05%	SEE TEXT	1	%				15545/33 AUG2002	CAPPUCCIO	FINETTI
083GKF01#00	(HUMIDITY) SAMPLE #1	2.07	1	%				15545/33 AUG2002	CAPPUCCIO	FINETTI
	(HUMIDITY) SAMPLE #2	2.1	1	%				15545/33 AUG2002	CAPPUCCIO	FINETTI
	(HUMIDITY) SAMPLE #3	2.2	1	%				15545/33 AUG2002	CAPPUCCIO	FINETTI
	AVERAGE HUMIDITY	2.12	1	%				15545/33 AUG2002	CAPPUCCIO	FINETTI





Analyses Report

Submission Id: 116953

Sample ID (Request No.) : 20022083

User sample ID (lot) : 183G03

Sample Type: SUD10398 (PNU290940AD) CAPSULE
25MG

Request Type: STABILITY

Stability Study: 183G03

Pack Type: 30 ml PLASTIC BOTTLE

Storage Condition: 25°C/60% U.R.

Time Label: 9 MONTHS

Preparation purpose: CLINICAL SUPPLY + STABILITY

Condition :
APPROVED

Status :
COMPLETE

Samples Notes:

Method	Controls	Results	Vers.	M.U.	Spec?	Lower lim	Upper lim	Book-Data Analyses	Analyst	Verifier
083GDS01#01	SAMPLE#1	89.91	1	%		80.000		1554/5/33 AUG2002	CAPPUCCIO	FINETTI
	SAMPLE#2	88.29	1	%		80.000		1554/5/33 AUG2002	CAPPUCCIO	FINETTI
	SAMPLE#3	96.41	1	%		80.000		1554/5/33 AUG2002	CAPPUCCIO	FINETTI
	SAMPLE#4	96.41	1	%		80.000		1554/5/33 AUG2002	CAPPUCCIO	FINETTI
	SAMPLE#5	91.00	1	%		80.000		1554/5/33 AUG2002	CAPPUCCIO	FINETTI
	SAMPLE#6	91.00	1	%		80.000		1554/5/33 AUG2002	CAPPUCCIO	FINETTI
	DISSOLUTION	92.17	1	%		80.000		1554/5/33 AUG2002	CAPPUCCIO	FINETTI
	STANDARD DEVIATION	3.431	1	std-1				1554/5/33 AUG2002	CAPPUCCIO	FINETTI
	C.V.	3.72	1	%				1554/5/33 AUG2002	CAPPUCCIO	FINETTI
	MIN. DISSOLUTION VALUE	88.29	1	%		80.000		1554/5/33 AUG2002	CAPPUCCIO	FINETTI
	MAX. DISSOLUTION VALUE	96.41	1	%		80.000		1554/5/33 AUG2002	CAPPUCCIO	FINETTI

Submission Id: 116953

Sample ID (Request No.): 20022083

User sample ID (lot): 183G03

Sample Type: SU010398 (PNU200940AD) CAPSULE
25MG

Request Type: STABILITY

Stability Study: 183G03

Pack Type: 30 ml PLASTIC BOTTLE

Storage Condition: 25°C/60% U.R.

Time Label: 9 MONTHS

Preparation purpose: CLINICAL SUPPLY + STABILITY

Condition :

APPROVED

Status :

COMPLETE

Samples Notes:

Observations on the Method 083GCO02#00, component: CAPSULE APPEARANCE

Opaque brick red colored, format 3, hard gelatin capsule

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Submission Id: 116953

Sample ID (Request No.): 20022083

User sample ID (lot): I83G03

Sample Type: SU010398 (PNU290940AD) CAPSULE
25MG

Request Type: STABILITY

Stability Study: I83G03

Pack Type: 30 ml PLASTIC BOTTLE

Storage Condition: 25°C/60% U.R.

Time Label: 9 MONTHS

Preparation purpose: CLINICAL SUPPLY + STABILITY

Condition :
APPROVED

Status :
COMPLETE

Samples Notes:

Observations on the Method 083GCO02#00, component: CAPSULE APPEARANCE
containing yellow-orange powder

Observations on the Method 083GDS01#01, component: DISSOLUTION
Average dissolution at 15 minutes: 74.93% (interval 63.91%-83.97%)

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Submission Id: 116953

Sample ID (Request No.): 20022083

User sample ID (lot): 183G03

Sample Type: SU010398 (PNU290940AD) CAPSULE
25MG

Request Type: STABILITY

Stability study: 183G03

Pack Type: 30 ml PLASTIC BOTTLE

Storage Condition: 25°C/60% U.R.

Time Label: 9 MONTHS

Preparation purpose: CLINICAL SUPPLY + STABILITY

Condition :
APPROVED

Status :
COMPLETE

Samples Notes:

Observations on the Method 083GDS01#01, component: DISSOLUTION

Average dissolution at 45 minutes: 96.56% (interval 95.33%-98.04%)

Observations on the Method 083GSC01#00, component: IMPURITIES NOT LESS THAN 0.05%

Total correlated substances: 0.32%



Submission Id: 116953
Sample ID (Request No.): 20022083

User sample ID (lot) 183G03

Sample Type: SU010398 (PNU280940AD) CAPSULE
25MG

Request Type: STABILITY
Stability Study: 183G03

Pack Type: 30 ml PLASTIC BOTTLE

Storage Condition: 25°C/60% U.R.

Time Label: 9 MONTHS

Preparation purpose: CLINICAL SUPPLY + STABILITY

Condition :
APPROVED

Status :
COMPLETE

Samples Notes:

Observations on the Method 083GSC01#00, component: IMPURITIES NOT LESS THAN 0.05%



Analyses Report

Submission Id: 116953	Request Type: STABILITY	Condition : APPROVED
Sample ID (Request No.) 20022083	Stability Study: I83G03	Status : COMPLETE
User sample ID (lot) I83G03	Pack Type: 30 ml PLASTIC BOTTLE	
Sample Type: SUD10398 (PNU290940AD) CAPSULE	Storage Condition: 25°C/60% U.R.	
25MG	Time Label: 9 MONTHS	
	Preparation purpose: CLINICAL SUPPLY + STABILITY	

Samples Notes:

Observations on the Method 083GSC01#00, component: IMPURITIES NOT LESS THAN 0.05%

RRT	AREA%
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Submission Id: 116953

Sample ID (Request No.): 20022083

User sample ID (lot): **I83G03**

Sample Type: **SUJ010398 (PNU290940AD) CAPSULE**
25MG

Request Type: STABILITY

Stability Study: I83G03

Pack Type: 30 ml PLASTIC BOTTLE

Storage Condition: 25°C/60% U.R.

Time Label: 9 MONTHS

Preparation purpose: CLINICAL SUPPLY + STABILITY

Condition :

APPROVED

Status :

COMPLETE

Samples Notes:

Observations on the Method

083GSC01#00, component: IMPURITIES NOT LESS THAN 0.05%

0.66

0.11

Submission id: 116953	Request Type: STABILITY	Condition : APPROVED
Sample ID (Request No.) 20022083	Stability Study: I83G03	Status : COMPLETE
User sample ID (lot) I83G03	Pack Type: 30 ml PLASTIC BOTTLE	
Sample Type: SU010398 (PNU290940AD) CAPSULE	Storage Condition: 25°C/60% U.R.	
25MG	Time Label: 9 MONTHS	
	Preparation purpose: CLINICAL SUPPLY + STABILITY	

Samples Notes:

Observations on the Method 083GSC01#00, component: IMPURITIES NOT LESS THAN 0.05%

0.94 0.05

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Submission Id: 118953

Sample ID (Request No.): 20022083

User sample ID (lot) 183G03

Sample Type: SU010398 (PNU250940AD) CAPSULE
25MG

Request Type: STABILITY

Stability Study: 183G03

Pack Type: 30 ml PLASTIC BOTTLE

Storage Condition: 25°C/60% U.R.

Time Label: 9 MONTHS

Preparation purpose: CLINICAL SUPPLY + STABILITY

Condition:

APPROVED

Status:

COMPLETE

Samples Notes:

Observations on the Method 083GSC01#00, component: IMPURITIES NOT LESS THAN 0.05%

1.00 99.68 (SU11248)

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Submission Id: 116953
 Sample ID (Request No.): 20022083
 User sample ID (lot): I83G03
 Sample Type: SU010398 (PNU/290940AD) CAPSULE 25MG
 Request Type: STABILITY
 Stability Study: I83G03
 Pack Type: 30 ml PLASTIC BOTTLE
 Storage Condition: 25°C/60% U.R.
 Time Label: 9 MONTHS
 Preparation purpose: CLINICAL SUPPLY + STABILITY
 Condition: **APPROVED**
 Status: **COMPLETE**

Samples Notes:

Observations on the Method 083GSC01#00, component: IMPURITIES NOT LESS THAN 0.05%

1.06 0.18

SUBMISSION APPROVED BY Volker ECK
APPROVE DATE 15-may-2003

SAMPLE APPROVED BY: GIORGIO FINETTI
APPROVE DATE: 03-sep-2002

Submission Id: 117497
Sample ID (Request No.): 20022972
User sample ID (Job): 183G03

Sample Type: SU010398 (PNU290940AD) CAPSULE
25MG

Request Type: STABILITY
Stability Study: 183G03

Pack Type: 30 ml PLASTIC BOTTLE
Storage Condition: 25°C/60% U.R.

Time Label: 12 MONTHS

Preparation purpose: CLINICAL SUPPLY + STABILITY

Condition :
APPROVED

Status :
COMPLETE

Samples Notes:

Method	Controls	Results	Vers.	M.U.	Spec?	Lower lim	Upper lim	Book-Data Analyses	Analyst	Verifier
083GCO02#00	CAPSULE APPEARANCE	0=UNCHANGED	1	bt				1554/59- NOV 2002	CAPPUCCIO	MACCARI
	CAPSULE COLOR	0=UNCHANGED	1	bt				1554/59- NOV 2002	CAPPUCCIO	MACCARI
	CONTENT APPEARANCE	0=UNCHANGED	1	bt				1554/59- NOV 2002	CAPPUCCIO	MACCARI
	CONTENT COLOR	0=UNCHANGED	1	bt				1554/59- NOV 2002	CAPPUCCIO	MACCARI
	SMELL	0=UNCHANGED	1	bt				1554/59- NOV 2002	CAPPUCCIO	MACCARI
083GT01#01_S	(HPLC TITER) SAMPLE#1	95.84	1	%		90.000	- 110.000	1554/59- NOV 2002	CAPPUCCIO	MACCARI
	(HPLC TITER) SAMPLE#2	96.17	1	%		90.000	- 110.000	1554/59- NOV 2002	CAPPUCCIO	MACCARI
	(HPLC TITER) SAMPLE#3	97.03	1	%		90.000	- 110.000	1554/59- NOV 2002	CAPPUCCIO	MACCARI
	AVERAGE TITER (HPLC)	96.35	1	%		90.000	- 110.000	1554/59- NOV 2002	CAPPUCCIO	MACCARI
	TOTAL CORRELATED SUBSTANCES	0.15	1	%				1554/59- NOV 2002	CAPPUCCIO	MACCARI
083GSC01#00	IMPURITIES NOT LESS THAN 0.05%	SEE TEXT	1	%				1554/59- NOV 2002	CAPPUCCIO	MACCARI
	(HUMIDITY) SAMPLE #1	2.1	1	%				1554/59- NOV 2002	CAPPUCCIO	MACCARI
083GKF01#00	(HUMIDITY) SAMPLE #2	2.2	1	%				1554/59- NOV 2002	CAPPUCCIO	MACCARI
	(HUMIDITY) SAMPLE #3	2.1	1	%				1554/59- NOV 2002	CAPPUCCIO	MACCARI
	AVERAGE HUMIDITY	2.13	1	%				1554/59- NOV 2002	CAPPUCCIO	MACCARI





Analyses Report

Submission Id: 117497
Sample ID (Request No.): 20022872
User sample ID (lot): I83G03

Sample Type: SU010398 (PNU290340AD) CAPSULE
25MG

Request Type: STABILITY
Stability Study: I83G03
Pack Type: 30 ml PLASTIC BOTTLE
Storage Condition: 25°C/60% U.R.
Time Label: 12 MONTHS
Preparation purpose: CLINICAL SUPPLY + STABILITY

Condition :
APPROVED
Status :
COMPLETE

Samples Notes:

Method	Controls	Results	Vers.	M.U.	Spec?	Lower lim	Upper lim	Book-Data Analyses	Analyst	Verifier
083GDS01#01	SAMPLE#1	88.22	1	%		80.000		15545/59- NOV 2002	CAPPUCCIO	MACCARI
	SAMPLE#2	93.41	1	%		80.000		15545/59- NOV 2002	CAPPUCCIO	MACCARI
	SAMPLE#3	101.19	1	%		80.000		15545/59- NOV 2002	CAPPUCCIO	MACCARI
	SAMPLE#4	97.04	1	%		80.000		15545/59- NOV 2002	CAPPUCCIO	MACCARI
	SAMPLE#5	94.97	1	%		80.000		15545/59- NOV 2002	CAPPUCCIO	MACCARI
	SAMPLE#6	92.89	1	%		80.000		15545/59- NOV 2002	CAPPUCCIO	MACCARI
	DISSOLUTION	94.62	1	%		80.000		15545/59- NOV 2002	CAPPUCCIO	MACCARI
	STANDARD DEVIATION	4.349	1	std-1				15545/59- NOV 2002	CAPPUCCIO	MACCARI
	C.V.	4.6	1	%				15545/59- NOV 2002	CAPPUCCIO	MACCARI
	MIN. DISSOLUTION VALUE	88.22	1	%		80.000		15545/59- NOV 2002	CAPPUCCIO	MACCARI
	MAX. DISSOLUTION VALUE	101.19	1	%		80.000		15545/59- NOV 2002	CAPPUCCIO	MACCARI

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Submission Id: 117497
Sample ID (Request No.): 20022972
User sample ID (lot): [83G03]

Sample Type: SU010398 (PNU290940AD) CAPSULE
25MG

Request Type: STABILITY
Stability Study: I83G03

Pack Type: 30 ml PLASTIC BOTTLE

Storage Condition: 25°C/60% U.R.

Time Label: 12 MONTHS

Preparation purpose: CLINICAL SUPPLY + STABILITY

Condition:
APPROVED

Status:
COMPLETE

Samples Notes:

Method	Controls	Results	Vers.	M.U.	Spec?	Lower lim	Upper lim	Book-Data Analyses	Analyst	Verifier
083GMD01#01 TOTAL AEROBIC BACTERIA	J	IN LIMITS	1	bt	ABSENT IN LIMITS NOT DETECTABLE NOT PLANNED	ABSENT IN LIMITS NOT DETECTABLE NOT PLANNED	ABSENT IN LIMITS NOT DETECTABLE NOT PLANNED	15545/59- NOV 2002	CAPPUCCIO	MACCARI
ESCHERICHIA COLI		ABSENT	1	bt	ABSENT NOT DETECTABLE NOT PLANNED	ABSENT NOT DETECTABLE NOT PLANNED	ABSENT NOT DETECTABLE NOT PLANNED	15545/59- NOV 2002	CAPPUCCIO	MACCARI
SALMONELLA		ABSENT	1	bt	ABSENT NOT DETECTABLE NOT PLANNED	ABSENT NOT DETECTABLE NOT PLANNED	ABSENT NOT DETECTABLE NOT PLANNED	15545/59- NOV 2002	CAPPUCCIO	MACCARI
FUNGI		IN LIMITS	1	bt	ABSENT IN LIMITS NOT DETECTABLE NOT PLANNED	ABSENT IN LIMITS NOT DETECTABLE NOT PLANNED	ABSENT IN LIMITS NOT DETECTABLE NOT PLANNED	15545/59- NOV 2002	CAPPUCCIO	MACCARI
STAPHYLOCOCCUS AUREUS		ABSENT	1	bt	ABSENT NOT DETECTABLE NOT PLANNED	ABSENT NOT DETECTABLE NOT PLANNED	ABSENT NOT DETECTABLE NOT PLANNED	15545/59- NOV 2002	CAPPUCCIO	MACCARI
ENTEROBACTERIA		IN LIMITS	1	bt	ABSENT IN LIMITS NOT DETECTABLE	ABSENT IN LIMITS NOT DETECTABLE	ABSENT IN LIMITS NOT DETECTABLE	15545/59- NOV 2002	CAPPUCCIO	MACCARI

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GIUSEPPE MACCARI

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Analyses Report

Submission Id: 117497
Sample ID (Request No.): 20022972
User sample ID (lot): 183G03
Sample Type: SU010398 (PNU290940AD) CAPSULE
25MG

Request Type: STABILITY
Stability Study: 183G03
Pack Type: 30 ml PLASTIC BOTTLE
Storage Condition: 25°C/60% U.R.
Time Label: 12 MONTHS
Preparation purpose: CLINICAL SUPPLY + STABILITY

Condition :
APPROVED
Status :
COMPLETE

Samples Notes:

Method	Controls	Results	Vers.	M.U.	Spec?	Lower lim	Upper lim	Book-Data Analyses	Analyst	Verifier
083GMC01#01	ENTEROBACTERIA	IN LIMITS	1	bx				NOT PLANNED		

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Submission Id: 117497

Sample ID (Request No.): 20022972

User sample ID (lot): I83G03

Sample Type: SU010398 (PNU290940AD) CAPSULE
25MG

Request Type: STABILITY

Stability Study: I83G03

Pack Type: 30 ml PLASTIC BOTTLE

Storage Condition: 25°C/80% U.R.

Time Label: 12 MONTHS

Preparation purpose: CLINICAL SUPPLY + STABILITY

Condition :

APPROVED

Status :

COMPLETE

Samples Notes:

Observations on the Method 083GCO02#00, component: CAPSULE APPEARANCE

Opaque brick red colored, format 3, hard gelatin capsule containing yellow-orange powder

Observations on the Method 083GDS01#01, component: DISSOLUTION

Average dissolution at 15 minutes: 77.24% (C.V.: 7.27%)

Submission Id: 117497

Sample ID (Request No.): 20022972

User sample ID (lot): I83G03

Sample Type: SU010398 (PNU290940AD) CAPSULE
25MG

Request Type: STABILITY

Stability Study: I83G03

Pack Type: 30 ml PLASTIC BOTTLE

Storage Condition: 25°C/60% UR.

Time Label: 12 MONTHS

Preparation purpose: CLINICAL SUPPLY + STABILITY

Condition :
APPROVED

Status :
COMPLETE

Samples Notes:

Observations on the Method 083GDS01#01, component: DISSOLUTION

Average dissolution 45 minutes: 97.39% (C.V.: 2.25%)

Observations on the Method 083GMC01#01, component: TOTAL AEROBIC BACTERIA

Total bacterial count < 10 Ufc/g (Report num. 02.16971)

Observations on the Method 083GMC01#01, component: ENTEROBACTERIA

Enterobacteria < 10 Ufc/g (Report num. 02.16971)

Observations on the Method 083GMC01#01, component: ESCHERICHIA COLI

Report num. 02.16971

Observations on the Method 083GMC01#01, component: FUNGI

Fungi (Yeasts + Molds) < 10 Ufc/g (Report num. 02.16971)

Observations on the Method 083GMC01#01, component: SALMONELLA

Report num. 02.16971

Observations on the Method 083GMC01#01, component: STAPHYLOCOCCUS AUREUS

Report num. 02.16971

Observations on the Method 083GSC01#00, component: IMPURITIES NOT LESS THAN 0.05%

Total correlated substances: 0.15%

Submission Id: 117497
Sample ID (Request No.): 20022972

User sample ID (lot): 183G03

Sample Type: SU010398 (PNU290940AD) CAPSULE
25MG

Request Type: STABILITY
Stability Study: 183G03

Pack Type: 30 ml PLASTIC BOTTLE

Storage Condition: 25°C/80% U.R.

Time Label: 12 MONTHS

Preparation purpose: CLINICAL SUPPLY + STABILITY

Condition :

APPROVED

Status :

COMPLETE

Samples Notes:

Observations on the Method 083GSC01400, component: IMPURITIES NOT LESS
THAN 0.05%

Submission Id: 117497

Sample ID (Request No.): 20022372

User sample ID (lot): 183G03

Sample Type: SUJ10398 (PNU280940AD) CAPSULE
25MG

Request Type: STABILITY

Stability Study: 183G03

Pack Type: 30 ml PLASTIC BOTTLE

Storage Condition: 25°C/60% U.R.

Time Label: 12 MONTHS

Preparation purpose: CLINICAL SUPPLY + STABILITY

Condition :
APPROVED

Status :
COMPLETE

Samples Notes:

Observations on the Method 083GC01#00, component: IMPURITIES NOT LESS THAN 0.05%

RRT

Area (%)

Submission Id: 117497

Sample ID (Request No.): 20022972

User sample ID (lot): 183G03

Sample Type: SUD10398 (PNU290940AD) CAPSULE
25MG

Request Type: STABILITY

Stability Study: 183G03

Pack Type: 30 ml PLASTIC BOTTLE

Storage Condition: 25°C/60% U.R.

Time Label: 12 MONTHS

Preparation purpose: CLINICAL SUPPLY + STABILITY

Condition:

APPROVED

Status:

COMPLETE

Samples Notes:

Observations on the Method 083GC01#00, component: IMPURITIES NOT LESS
THAN 0.05%

Submission Id: 117497
Sample ID (Request No.): 20022972
User sample ID (lot) **I83G03**
Sample Type: SUO10398 (PNU290940AD) CAPSULE
25MG

Request Type: STABILITY
Stability Study: I83G03
Pack Type: 30 ml PLASTIC BOTTLE
Storage Condition: 25°C/60% U.R.
Time Label: 12 MONTHS
Preparation purpose: CLINICAL SUPPLY + STABILITY

Condition :
APPROVED
Status :
COMPLETE

Samples Notes:

Observations on the Method 983GC01#00, component: IMPURITIES NOT LESS THAN 0.05%

0.65 0.10



Submission Id: 117497

Sample ID (Request No.): 20022872

User sample ID (lot) I83G03

Sample Type: SU010398 (PNU290940AD) CAPSULE
25MG

Request Type: STABILITY

Stability Study: I83G03

Pack Type: 30 ml PLASTIC BOTTLE

Storage Condition: 25°C/60% U.R.

Time Label: 12 MONTHS

Preparation purpose: CLINICAL SUPPLY + STABILITY

Condition :

APPROVED

Status :

COMPLETE

Samples Notes:

Observations on the Method

083GC01#00, component: IMPURITIES NOT LESS
THAN 0.05%

0.94

0.05

Condition :
APPROVED
Status :
COMPLETE

Request Type: STABILITY
Stability Study: I83G03
Pack Type: 30 ml PLASTIC BOTTLE
Storage Condition: 25°C/60% U.R.
Time Label: 12 MONTHS
Preparation purpose: CLINICAL SUPPLY + STABILITY

Submission Id: 117497
Sample ID (Request No.): 20022372
User sample ID (lot): **I83G03**
Sample Type: SU010398 (PNU290940AD) CAPSULE
25MG

Samples Notes:

Observations on the Method 083GC01#00, component: IMPURITIES NOT LESS THAN 0.05%

1.00 99.85 (SU 11248)

SUBMISSION APPROVED BY Volker ECK
APPROVE DATE 15-may-2003
SAMPLE APPROVED BY: GIUSEPPE MACCARI
APPROVE DATE: 27-nov-2002

Time Points

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Submission Id: 116953

Sample ID (Request No.): 20022083

User sample ID (lot): 183G03

Sample Date : 18/07/2002

Sample Type: SUD10398 (PNU290940AD) CAPSULE
2SMG

Stability Study Start Date : 18/10/2001

Stability Protocol Number : 2001017 - Manufacturer : PD/Pharmacia Nerviano

Samples Notes:

Batch Manufacture Date : 17/09/2001

Stability Study: 183G03

Pack Type: 30 ml PLASTIC BOTTLE

Storage Condition: 25°C/60% U.R.

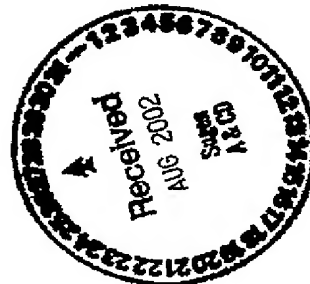
Time Label: 9 MONTHS

Preparation purpose: CLINICAL SUPPLY + STABILITY

Condition :
APPROVED

Status :
COMPLETE

Method	Controls	Results	Vers.	M.U.	Spec?	Lower lim	Upper lim	Book-Data Analyses	Analyst	Verifier
083GCC002#D 0	CAPSULE APPEARANCE	0=UNCHANGED						15545/32 AUG2002	CAPPUCCIO	FINETTI
	CAPSULE COLOR	0=UNCHANGED						15545/32 AUG2002	CAPPUCCIO	FINETTI
	CONTENT APPEARANCE	0=UNCHANGED						15545/32 AUG2002	CAPPUCCIO	FINETTI
	CONTENT COLOR	0=UNCHANGED						15545/32 AUG2002	CAPPUCCIO	FINETTI
	SMELL	0=UNCHANGED						15545/32 AUG2002	CAPPUCCIO	FINETTI
083GT01#01 _S	(HPLC TITER) SAMPLE#1	97.48	%			90.000	- 110.000	15545/32 AUG2002	CAPPUCCIO	FINETTI
	(HPLC TITER) SAMPLE#2	96.12	%			90.000	- 110.000	15545/32 AUG2002	CAPPUCCIO	FINETTI
	(HPLC TITER) SAMPLE#3	97.03	%			90.000	- 110.000	15545/32 AUG2002	CAPPUCCIO	FINETTI
	AVERAGE TITER (HPLC)	96.88	%			90.000	- 110.000	15545/32 AUG2002	CAPPUCCIO	FINETTI
	TOTAL CORRELATED SUBSTANCES	0.32	%					15545/32 AUG2002	CAPPUCCIO	FINETTI
083GSC01#0 0	IMPURITIES NOT LESS THAN 0.05%	SEE TEXT	%					15545/32 AUG2002	CAPPUCCIO	FINETTI
	(HUMIDITY) SAMPLE #1	2.07	%					15545/32 AUG2002	CAPPUCCIO	FINETTI
	(HUMIDITY) SAMPLE #2	2.1	%					15545/32 AUG2002	CAPPUCCIO	FINETTI
	(HUMIDITY) SAMPLE #3	2.2	%					15545/32 AUG2002	CAPPUCCIO	FINETTI
	AVERAGE HUMIDITY	2.12	%					15545/32 AUG2002	CAPPUCCIO	FINETTI



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Submission Id: 116953

Sample ID (Request No.): 20022083

User sample ID (lot): 183G03

Sample Date: 18/07/2002

Sample Type: SU010398 (PNU290940AD) CAPSULE
25MG

Stability Study Start Date: 18/10/2001

Stability Protocol Number: 2001017 - Manufacturer: PD/Pharmacia Nerviano

Samples Notes:

Batch Manufacture Date: 17/09/2001

Stability Study: 183G03

Pack Type: 30 ml PLASTIC BOTTLE

Storage Condition: 25°C/60% U.R.

Time Label: 9 MONTHS

Preparation purpose: CLINICAL SUPPLY + STABILITY

Condition:

APPROVED

Status:

COMPLETE

Method	Controls	Results	Vers.	M.U.	Spec?	Lower lim	Upper lim	Book-Data Analyses	Analyst	Verifier
083GDS01#0 1	SAMPLE#1	89.91		%		80.000		15545/32 AUG2002	CAPPUCCIO	FINETTI
	SAMPLE#2	88.29		%		80.000		15545/32 AUG2002	CAPPUCCIO	FINETTI
	SAMPLE#3	96.41		%		80.000		15545/32 AUG2002	CAPPUCCIO	FINETTI
	SAMPLE#4	96.41		%		80.000		15545/32 AUG2002	CAPPUCCIO	FINETTI
	SAMPLE#5	91.00		%		80.000		15545/32 AUG2002	CAPPUCCIO	FINETTI
	SAMPLE#6	91.00		%		80.000		15545/32 AUG2002	CAPPUCCIO	FINETTI
1	DISSOLUTION	92.17		%		80.000		15545/32 AUG2002	CAPPUCCIO	FINETTI
	STANDARD DEVIATION	3.431		std-1				15545/32 AUG2002	CAPPUCCIO	FINETTI
	C.V.	3.72		%				15545/32 AUG2002	CAPPUCCIO	FINETTI
	MIN. DISSOLUTION VALUE	88.29		%		80.000		15545/32 AUG2002	CAPPUCCIO	FINETTI
	MAX. DISSOLUTION VALUE	96.41		%		80.000		15545/32 AUG2002	CAPPUCCIO	FINETTI
								15545/32 AUG2002	CAPPUCCIO	FINETTI



Pharmaceutical Development

Submission Id: 116953
Sample ID (Request No.): 20022083
User sample ID (lot): 183G03
Sample date: 18/07/2002
Sample Type: SU010398 (PNU290940AD) CAPSULE
25MG
Stability Study Start Date: 18/10/2001
Stability Protocol Number: 2001017 - Manufacturer: PD/Pharmacia Nerviano

Batch Manufacture Date: 17/09/2001
Stability Study: 183G03
Pack Type: 30 ml PLASTIC BOTTLE
Storage Condition: 25°C/60% U.R.
Time Label: 9 MONTHS
Preparation purpose: CLINICAL SUPPLY + STABILITY

Condition: **APPROVED**
Status: **COMPLETE**

Samples Notes:

Observations on the Method 083GCO02#00, component: CAPSULE APPEARANCE
Opaque brick red colored, format 3, hard gelatin capsule containing red-orange powder
Observations on the Method 083GDS01#01, component: DISSOLUTION
Average dissolution at 15 minutes: 74.93% (interval 63.91%-89.37%)
Average dissolution at 45 minutes: 96.59% (interval 95.33%-98.04%)
Observations on the Method 083GSC01#00, component: IMPURITIES NOT LESS
THAN 0.05%

Total correlated substances: 0.32%

RRT	AREA%
0.66	0.11
0.94	0.05
1.00	99.68 (SU11248)
1.06	0.16

Approved by: FINETTI
Approval date: 05-aug-2002



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Pharmaceutical Development

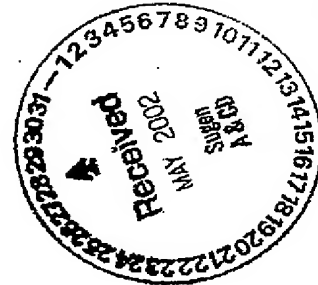
Submission id: 116305
Sample ID (Request No.): 20021134
User sample ID (lot): **183G03**
Sample Date : 18/04/2002
Sample Type: SU010398 (PNU290940AD) CAPSULE
25MG
Stability Study Start Date : 18/10/2001
Stability Protocol Number : 2001017 - Manufacturer : PD/Pharmacia Nerviano

Batch Manufacture Date : 17/09/2001
Stability Study: 183G03
Pack Type: 30 ml PLASTIC BOTTLE
Storage Condition: 25°C/60% U.R.
Time Label: 6 MONTHS
Preparation purpose: CLINICAL SUPPLY + STABILITY

Condition :
APPROVED
Status :
COMPLETE

Samples Notes:

Method	Controls	Results	M.U.	Spec?	Lower lim	Upper lim	Book-Data Analyses	Analyst	Verifier
083GCC02#0	CAPSULE APPEARANCE	0=UNCHANGED	bt				15545/18- MAY 2002	CAPPUCCIO	MARIANI
	CAPSULE COLOR	0=UNCHANGED	bt				15545/18- MAY 2002	CAPPUCCIO	MARIANI
	CONTENT APPEARANCE	0=UNCHANGED	bt				15545/18- MAY 2002	CAPPUCCIO	MARIANI
	CONTENT COLOR	0=UNCHANGED	bt				15545/18- MAY 2002	CAPPUCCIO	MARIANI
	SMELL	0=UNCHANGED	bt				15545/18- MAY 2002	CAPPUCCIO	MARIANI
083GTI01#01 -S	(HPLC TITER) SAMPLE#1	97.95	%		90.000	110.000	15545/18- MAY 2002	CAPPUCCIO	MARIANI
	(HPLC TITER) SAMPLE#2	97.96	%		90.000	110.000	15545/18- MAY 2002	CAPPUCCIO	MARIANI
	(HPLC TITER) SAMPLE#3	97.25	%		90.000	110.000	15545/18- MAY 2002	CAPPUCCIO	MARIANI
	AVERAGE TITER (HPLC)	97.72	%		90.000	110.000	15545/18- MAY 2002	CAPPUCCIO	MARIANI
	TOTAL CORRELATED SUBSTANCES	0.18	%				15545/18- MAY 2002	CAPPUCCIO	MARIANI
083GSC01#0	IMPURITIES NOT LESS THAN 0.05%	SEE TEXT	%				15545/18- MAY 2002	CAPPUCCIO	MARIANI
	(HUMIDITY) SAMPLE #1	2.37	%				15545/18- MAY 2002	CAPPUCCIO	MARIANI
	(HUMIDITY) SAMPLE #2	2.4	%				15545/18- MAY 2002	CAPPUCCIO	MARIANI
	(HUMIDITY) SAMPLE #3	2.36	%				15545/18- MAY 2002	CAPPUCCIO	MARIANI
	AVERAGE HUMIDITY	2.36	%				15545/18- MAY 2002	CAPPUCCIO	MARIANI



Submission Id: 116305

Sample ID (Request No.): 20021134

User sample ID (Lot): 183G03

Sample Date : 18/04/2002

Sample Type: SU010398 (PNU290940AD) CAPSULE
25MG

Stability Study Start Date : 18/10/2001

Stability Protocol Number : 2001017 - Manufacturer : PD/Pharmacia Nerviano

Samples Notes:

Batch Manufacture Date : 17/09/2001

Stability Study: 183G03

Pack Type: 30 ml PLASTIC BOTTLE

Storage Condition: 25°C/60% U.R.

Time Label: 6 MONTHS

Preparation purpose: CLINICAL SUPPLY + STABILITY

Condition :
APPROVED

Status :
COMPLETE

Method	Controls	Results	M.U.	Spec?	Lower lim	Upper lim	Book-Data Analyses	Analyst	Verifier
083GDS01#0 1	SAMPLE#1	94.01	%		80.000		15545/18- MAY 2002	CAPPUCCIO	MARIANI
	SAMPLE#2	99.04	%		80.000		15545/18- MAY 2002	CAPPUCCIO	MARIANI
	SAMPLE#3	100.16	%		80.000		15545/18- MAY 2002	CAPPUCCIO	MARIANI
	SAMPLE#4	94.01	%		80.000		15545/18- MAY 2002	CAPPUCCIO	MARIANI
	SAMPLE#5	88.41	%		80.000		15545/18- MAY 2002	CAPPUCCIO	MARIANI
	SAMPLE#6	94.56	%		80.000		15545/18- MAY 2002	CAPPUCCIO	MARIANI
	DISSOLUTION	95.03	%		80.000		15545/18- MAY 2002	CAPPUCCIO	MARIANI
	STANDARD DEVIATION	4.208	std-1				15545/18- MAY 2002	CAPPUCCIO	MARIANI
	C.V.	4.43	%				15545/18- MAY 2002	CAPPUCCIO	MARIANI
	MIN. DISSOLUTION VALUE	88.41	%		80.000		15545/18- MAY 2002	CAPPUCCIO	MARIANI
	MAX. DISSOLUTION VALUE	100.16	%		80.000		15545/18- MAY 2002	CAPPUCCIO	MARIANI

Submission Id: 116305
Sample ID (Request No.) 20021134
User sample ID (lot) 183G03
Sample Date : 18/04/2002
Sample Type: SU010398 (PNU280940AD) CAPSULE
25MG

Stability Study Start Date : 18/10/2001
Stability Protocol Number : 2001017 - Manufacturer : PD/Pharmacia Nerviano

Samples Notes:

Observations on the Method 083GCO2#00, component: CAPSULE APPEARANCE

Opaque brick red colored, format 3, hard gelatin capsule containing red-orange powder

Observations on the Method 083GDS01#01, component: DISSOLUTION

Dissolution at 15 minutes: 76.5 % (C.V.= 13.9%)

Dissolution at 45 minutes: 99.97% (C.V.= 1.16%)

Observations on the Method 083GSC01#00, component: IMPURITIES NOT LESS

THAN 0.05%

Total correlated substances: 0.18%

RRT	Area (%)
0.66	0.12
0.91	0.06
1.00	99.82 (SU11248)

Condition :
APPROVED
Status :
COMPLETE

Batch Manufacture Date : 17/09/2001
Stability Study: 183G03
Pack Type: 30 ml PLASTIC BOTTLE
Storage Condition: 25°C/60% U.R.
Time Label: 6 MONTHS
Preparation purpose: CLINICAL SUPPLY + STABILITY

Approved by: MARIANI
Approval date: 17-may-2002

PHARMACIA

Pharmaceutical Development

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Submission Id: 116307

Sample ID (Request No.): 20021136

User sample ID (lot): 183G03

Sample Date : 18/04/2002

Sample Type: SU010398 (PNU2B0840AD) CAPSULE
25MG

Stability Study Start Date : 18/10/2001

Stability Protocol Number : 2001017 - Manufacturer : PD/Pharmacia Nerviano

Samples Notes:

Batch Manufacture Date : 17/09/2001

Stability Study: 183G03

Pack Type: 30 ml PLASTIC BOTTLE

Storage Condition: 40°C/75% U.R.

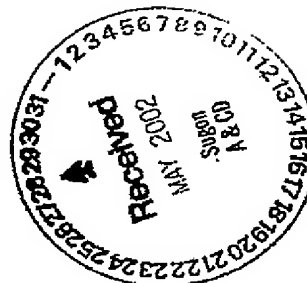
Time Label: 6 MONTHS

Preparation purpose: CLINICAL SUPPLY + STABILITY

Condition :
APPROVED

Status :
COMPLETE

Method	Controls	Results	M.U.	Spec?	Lower lim	Upper lim	Book-Data Analyses	Analyst	Verifier
083G0002#0	CAPSULE APPEARANCE	0=UNCHANGED	txt				15545/18- MAY 2002	CAPPUCCIO	MARIANI
	CAPSULE COLOR	0=UNCHANGED	txt				15545/18- MAY 2002	CAPPUCCIO	MARIANI
	CONTENT APPEARANCE	0=UNCHANGED	txt				15545/18- MAY 2002	CAPPUCCIO	MARIANI
	CONTENT COLOR	0=UNCHANGED	txt				15545/18- MAY 2002	CAPPUCCIO	MARIANI
	SMELL	0=UNCHANGED	txt				15545/18- MAY 2002	CAPPUCCIO	MARIANI
083GT01#01 _S	(HPLC TITER) SAMPLE#1	97.43	%		90.000	110.000	15545/18- MAY 2002	CAPPUCCIO	MARIANI
	(HPLC TITER) SAMPLE#2	98.55	%		90.000	110.000	15545/18- MAY 2002	CAPPUCCIO	MARIANI
	(HPLC TITER) SAMPLE#3	97.23	%		90.000	110.000	15545/18- MAY 2002	CAPPUCCIO	MARIANI
	AVERAGE TITER (HPLC)	97.74	%		90.000	110.000	15545/18- MAY 2002	CAPPUCCIO	MARIANI
083GSC01#0	TOTAL CORRELATED SUBSTANCES	0.21	%				15545/18- MAY 2002	CAPPUCCIO	MARIANI
	IMPURITIES NOT LESS THAN 0.05%	SEE TEXT	%				15545/18- MAY 2002	CAPPUCCIO	MARIANI
083GKF01#00	(HUMIDITY) SAMPLE #1	2.77	%				15545/18- MAY 2002	CAPPUCCIO	MARIANI
	(HUMIDITY) SAMPLE #2	2.9	%				15545/18- MAY 2002	CAPPUCCIO	MARIANI
	(HUMIDITY) SAMPLE #3	2.8	%				15545/18- MAY 2002	CAPPUCCIO	MARIANI
	AVERAGE HUMIDITY	2.82	%				15545/18- MAY 2002	CAPPUCCIO	MARIANI



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by MARIANI

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Submission Id: 116307
Sample ID (Request No.): 20021136
User sample ID (lot): I83G03
Sample Date: 18/04/2002
Sample Type: SU010398 (PNU290940AD) CAPSULE
25MG
Stability Study Start Date: 18/10/2001
Stability Protocol Number: 2001017 - Manufacturer: PD/Pharmacia Nerviano

Batch Manufacture Date: 17/09/2001
Stability Study: I83G03
Pack Type: 30 ml PLASTIC BOTTLE
Storage Condition: 40°C/75% U.R.
Time Label: 6 MONTHS
Preparation purpose: CLINICAL SUPPLY + STABILITY

Condition: **APPROVED**
Status: **COMPLETE**

Samples Notes:

Method	Controls	Results	M.U.	Spec?	Lower lim	Upper lim	Book-Data Analyses	Analyst	Verifier
083GDS01#0 1	SAMPLE#1	96.29	%		80.000		15545/18- MAY 2002	CAPPUCCIO	MARIANI
	SAMPLE#2	95.75	%		80.000		15545/18- MAY 2002	CAPPUCCIO	MARIANI
	SAMPLE#3	96.82	%		80.000		15545/18- MAY 2002	CAPPUCCIO	MARIANI
	SAMPLE#4	100.05	%		80.000		15545/18- MAY 2002	CAPPUCCIO	MARIANI
	SAMPLE#5	99.51	%		80.000		15545/18- MAY 2002	CAPPUCCIO	MARIANI
	SAMPLE#6	97.90	%		80.000		15545/18- MAY 2002	CAPPUCCIO	MARIANI
	DISSOLUTION	97.72	%		80.000		15545/18- MAY 2002	CAPPUCCIO	MARIANI
	STANDARD DEVIATION	1.755	std-1				15545/18- MAY 2002	CAPPUCCIO	MARIANI
	C.V.	1.8	%				15545/18- MAY 2002	CAPPUCCIO	MARIANI
	MIN. DISSOLUTION VALUE	96.75	%		80.000		15545/18- MAY 2002	CAPPUCCIO	MARIANI
	MAX. DISSOLUTION VALUE	100.05	%		80.000		15545/18- MAY 2002	CAPPUCCIO	MARIANI



Pharmaceutical Development

Submission Id: 116307
 Sample ID (Request No.): 20021136
 User sample ID (lot): **183G03**
 Sample Date : 18/04/2002
 Sample Type: SU010398 (PNU290940AD) CAPSULE
 25MG
 Stability Study Start Date : 18/10/2001
 Stability Protocol Number : 2001017 - Manufacturer : PD/Pharmacia Nerviano
 Batch Manufacture Date : 17/09/2001
 Stability Study: 183G03
 Pack Type: 30 ml PLASTIC BOTTLE
 Storage Condition: 40°C/75% U.R.
 Time Label: 6 MONTHS
 Preparation purpose: CLINICAL SUPPLY + STABILITY

Condition :
APPROVED
 Status :
COMPLETE

Samples Notes:

Observations on the Method 083GCO02#00, component: CAPSULE APPEARANCE
 Opaque brick red colored, format 3, hard gelatin capsule containing red-orange powder
 Observations on the Method 083GDS01#01, component: DISSOLUTION
 Dissolution at 15 minutes: 96.74% (C.V. = 1.77%)
 Dissolution at 45 minutes: 97.72% (C.V. = 1.86%)
 Observations on the Method 083GSC01#00, component: IMPURITIES NOT LESS
 THAN 0.05%

Total correlated substances: 0.21%

RRT	Area (%)
0.66	0.08
0.91	0.06
0.94	0.07
1.00	99.79 (SU11248)

Approved by: MARIANI
 Approval date: 17-may-2002

Submission Id: 115471

Sample ID (Request No.): 20020165

User sample ID (ict): 183G03

Sample Date : 18/01/2002

Sample Type: SU010398 (PNU290940AD) CAPSULE
25MG

Stability Study Start Date : 18/10/2001

Stability Protocol Number : 2001017 - Manufacturer : PD/Pharmacia Nerviano

Samples Notes:

Batch Manufacture Date : 17/09/2001

Request Type: RELEASE

Stability Study: 183G03

Pack Type: 30 ml PLASTIC BOTTLE

Storage Condition: 25°C/60% U.R.

Time Label: 3 MONTHS

Preparation purpose: CLINICAL SUPPLY + STABILITY

Condition :
APPROVED

Status :
COMPLETE

Method	Controls	Results	M.U.	Spec?	Lower lim	Upper lim	Book-Data Analyses	Analyst	Verifier
083GCO02#0 0	CAPSULE APPEARANCE	0=UNCHANGED	bt				143/44- JAN 2002	CAPPUCCIO	MACCARI
	CAPSULE COLOR	0=UNCHANGED	bt				143/44- JAN 2002	CAPPUCCIO	MACCARI
	CONTENT APPEARANCE	0=UNCHANGED	bt				143/44- JAN 2002	CAPPUCCIO	MACCARI
	CONTENT COLOR	0=UNCHANGED	bt				143/44- JAN 2002	CAPPUCCIO	MACCARI
	SMELL	0=UNCHANGED	bt				143/44- JAN 2002	CAPPUCCIO	MACCARI
083GT01#01 _S	(HPLC TITER) SAMPLE#1	96.84	%		90.000	110.000	143/44- JAN 2002	CAPPUCCIO	MACCARI
	(HPLC TITER) SAMPLE#2	96.31	%		90.000	110.000	143/44- JAN 2002	CAPPUCCIO	MACCARI
	(HPLC TITER) SAMPLE#3	96.41	%		90.000	110.000	143/44- JAN 2002	CAPPUCCIO	MACCARI
	AVERAGE TITER (HPLC)	97.19	%		90.000	110.000	143/44- JAN 2002	CAPPUCCIO	MACCARI
	TOTAL CORRELATED SUBSTANCES	0.21	%				143/44- JAN 2002	CAPPUCCIO	MACCARI
083GSC01#0 0	IMPURITIES NOT LESS THAN 0.05%	SEE TEXT	%				143/44- JAN 2002	CAPPUCCIO	MACCARI
	(HUMIDITY) SAMPLE #1	1.9	%				143/44- JAN 2002	CAPPUCCIO	MACCARI
083GKF01#00	(HUMIDITY) SAMPLE #2	1.82	%				143/44- JAN 2002	CAPPUCCIO	MACCARI
	(HUMIDITY) SAMPLE #3	1.9	%				143/44- JAN 2002	CAPPUCCIO	MACCARI
	AVERAGE HUMIDITY	1.87	%				143/44- JAN 2002	CAPPUCCIO	MACCARI

Submission Id: 115471

Sample ID (Request No.): 20020165

User sample ID (lot): **183G03**

Sample Date: 18/01/2002

Sample Type: SU010398 (PNU290940AD) CAPSULE
25MG

Stability Study Start Date: 18/10/2001

Stability Protocol Number: 2001017 - Manufacturer: PD/Pharmacia Nerviano

Samples Notes:

Batch Manufacture Date: 17/09/2001

Request Type: RELEASE

Stability Study: 183G03

Pack Type: 30 ml PLASTIC BOTTLE

Storage Condition: 25°C/60% U.R.

Time Label: 3 MONTHS

Preparation purpose: CLINICAL SUPPLY + STABILITY

Condition :
APPROVED

Status :
COMPLETE

Method	Controls	Results	M.U.	Spec?	Lower lim	Upper lim	Book-Data Analyses	Analyst	Verifier
083GDS01#0 1	SAMPLE#1	101.14	%		80.000		143/44- JAN 2002	CAPPUCCIO	MACCARI
	SAMPLE#2	106.48	%		80.000		143/44- JAN 2002	CAPPUCCIO	MACCARI
	SAMPLE#3	109.97	%		80.000		143/44- JAN 2002	CAPPUCCIO	MACCARI
	SAMPLE#4	106.90	%		80.000		143/44- JAN 2002	CAPPUCCIO	MACCARI
	SAMPLE#5	105.33	%		80.000		143/44- JAN 2002	CAPPUCCIO	MACCARI
	SAMPLE#6	104.08	%		80.000		143/44- JAN 2002	CAPPUCCIO	MACCARI
	DISSOLUTION	105.65	%		80.000		143/44- JAN 2002	CAPPUCCIO	MACCARI
	STANDARD DEVIATION	2.96	std-1				143/44- JAN 2002	CAPPUCCIO	MACCARI
	C.V.	2.8	%				143/44- JAN 2002	CAPPUCCIO	MACCARI
	MIN. DISSOLUTION VALUE	101.14	%		80.000		143/44- JAN 2002	CAPPUCCIO	MACCARI
	MAX. DISSOLUTION VALUE	109.97	%		80.000		143/44- JAN 2002	CAPPUCCIO	MACCARI

Submission Id: 115471

Sample ID (Request No.): 20020165

User sample ID (lot): 183G03

Sample Date : 18/01/2002

Sample Type: SUJ010398 (PNU230940AD) CAPSULE
25MG

Stability Study Start Date : 18/10/2001

Stability Protocol Number : 2001017 - Manufacturer : PD/Pharmacia Nerviano

Batch Manufacture Date : 17/09/2001

Request Type: RELEASE

Stability Study: 183G03

Pack Type: 30 ml PLASTIC BOTTLE

Storage Condition: 25°C/60% U.R.

Time Label: 3 MONTHS

Preparation purpose: CLINICAL SUPPLY + STABILITY

Condition :
APPROVED

Status:
COMPLETE

Samples Notes:

Observations on the Method 083GCO02#00, component: CAPSULE APPEARANCE

Opaque brick red colored, format 3, hard gelatin capsule containing yellow-orange powder

Observations on the Method 083GDS01#01, component: DISSOLUTION

Observations on the Method 083GSC01#00, component: IMPURITIES NOT LESS THAN 0.05%

Total correlated substances: 0.21%

RRT	Area (%)
1.00	99.79 (SU 11248)
1.97	0.09
2.06	0.12

Approved by: MACCARI
Approval date: 04-feb-2002



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Submission Id: 115473

Sample ID (Request No.): 20020187

User sample ID (lot): 183G03

Sample Date : 18/01/2002

Sample Type: SU010398 (PNU290940AD)CAPSULE
25MG

Stability Study Start Date : 18/10/2001

Stability Protocol Number : 2001017 - Manufacturer : PD/Pharmacia Nerviano

Samples Notes:

Batch Manufacture Date : 17/09/2001

Request Type: RELEASE

Stability Study: 183G03

Pack Type: 30 ml PLASTIC BOTTLE

Storage Condition: 40°C/75% U.R.

Time Label: 3 MONTHS

Preparation purpose: CLINICAL SUPPLY + STABILITY

Condition :
APPROVED

Status :
COMPLETE

Method	Controls	Results	M.U.	Spec?	Lower lim	Upper lim	Book-Data Analyses	Analyst	Verifier
083GCO02#0	CAPSULE APPEARANCE	0=UNCHANGED	bt				143/44- JAN 2002	CAPPUCCIO	MACCARI
	CAPSULE COLOR	0=UNCHANGED	bt				143/44- JAN 2002	CAPPUCCIO	MACCARI
	CONTENT APPEARANCE	0=UNCHANGED	bt				143/44- JAN 2002	CAPPUCCIO	MACCARI
	CONTENT COLOR	0=UNCHANGED	bt				143/44- JAN 2002	CAPPUCCIO	MACCARI
	SMELL	0=UNCHANGED	bt				143/44- JAN 2002	CAPPUCCIO	MACCARI
083GT01#01 _S	(HPLC TITER) SAMPLE#1	99.21	%		90.000	110.000	143/44-JAN 2002	CAPPUCCIO	MACCARI
	(HPLC TITER) SAMPLE#2	96.18	%		90.000	110.000	143/44-JAN 2002	CAPPUCCIO	MACCARI
	(HPLC TITER) SAMPLE#3	95.82	%		90.000	110.000	143/44-JAN 2002	CAPPUCCIO	MACCARI
	AVERAGE TITER (HPLC)	97.07	%		90.000	110.000	143/44-JAN 2002	CAPPUCCIO	MACCARI
	TOTAL CORRELATED SUBSTANCES	0.41	%				143/44- JAN 2002	CAPPUCCIO	MACCARI
083GSC01#0	IMPURITIES NOT LESS THAN 0.05%	SEE TEXT	%				143/44- JAN 2002	CAPPUCCIO	MACCARI
	(HUMIDITY) SAMPLE #1	1.8	%				143/44- JAN 2002	CAPPUCCIO	MACCARI
083GKF01#00	(HUMIDITY) SAMPLE #2	1.7	%				143/44- JAN 2002	CAPPUCCIO	MACCARI
	(HUMIDITY) SAMPLE #3	1.9	%				143/44- JAN 2002	CAPPUCCIO	MACCARI
	AVERAGE HUMIDITY	1.8	%				143/44- JAN 2002	CAPPUCCIO	MACCARI



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Submission Id: 115473

Sample ID (Request No.): 20020167

User sample ID (lot): 183G03

Sample Date : 18/01/2002

Sample Type: SU010398 (PNU290940AD) CAPSULE
25MG

Stability Study Start Date : 18/10/2001

Stability Protocol Number : 2001017 - Manufacturer : PD/Pharmacia Nerviano

Samples Notes:

Batch Manufacture Date : 17/09/2001

Request Type: RELEASE

Stability Study: 183G03

Pack Type: 30 ml PLASTIC BOTTLE

Storage Condition: 40°C/75% U.R.

Time Label: 3 MONTHS

Preparation purpose: CLINICAL SUPPLY + STABILITY

Condition :
APPROVED

Status :
COMPLETE

Method	Controls	Results	M.U.	Spec?	Lower lim	Upper lim	Book-Data Analyses	Analyst	Verifier
083GDS01H0 1	SAMPLE#1	101.47	%		80.000		143/44- JAN 2002	CAPPUCCIO	MACCARI
	SAMPLE#2	102.93	%		80.000		143/44- JAN 2002	CAPPUCCIO	MACCARI
	SAMPLE#3	104.56	%		80.000		143/44- JAN 2002	CAPPUCCIO	MACCARI
	SAMPLE#4	106.96	%		80.000		143/44- JAN 2002	CAPPUCCIO	MACCARI
	SAMPLE#5	101.34	%		80.000		143/44- JAN 2002	CAPPUCCIO	MACCARI
	SAMPLE#6	98.51	%		80.000		143/44- JAN 2002	CAPPUCCIO	MACCARI
	DISSOLUTION	102.63	%		80.000		143/44- JAN 2002	CAPPUCCIO	MACCARI
	STANDARD DEVIATION	2.917	std-1				143/44- JAN 2002	CAPPUCCIO	MACCARI
	C.V.	2.84	%				143/44- JAN 2002	CAPPUCCIO	MACCARI
	MIN. DISSOLUTION VALUE	98.51	%		80.000		143/44- JAN 2002	CAPPUCCIO	MACCARI
	MAX. DISSOLUTION VALUE	106.96	%		80.000		143/44- JAN 2002	CAPPUCCIO	MACCARI



Submission Id: 115473
 Sample ID (Request No.): 20020167
 User sample ID (lot): 183G03
 Sample Date : 18/01/2002
 Sample Type: SU010398 (PNU290940AD) CAPSULE
 25MG
 Stability Study Start Date : 18/10/2001
 Stability Protocol Number : 2001017 - Manufacturer : PD/Pharmacia Nerviano
 Samples Notes:
 Batch Manufacture Date : 17/09/2001
 Request Type: RELEASE
 Stability Study: 183G03
 Pack Type: 30 ml PLASTIC BOTTLE
 Storage Condition: 40°C/75% U.R.
 Time Label: 3 MONTHS
 Preparation purpose: CLINICAL SUPPLY + STABILITY
 Condition : **APPROVED**
 Status : **COMPLETE**

Observations on the Method 083GCC02#00, component: CAPSULE APPEARANCE
 Opaque brick red colored, format 3, hard gelatin capsule containing yellow-orange powder
 Observations on the Method 083GDS01#01, component: DISSOLUTION

Observations on the Method 083GSC01#00, component: IMPURITIES NOT LESS
 THAN 0.05%

Total correlated substances: 0.41%

RRT	Area (%)
0.94	0.05
1.00	99.60 (SU 11248)
1.97	0.07
2.06	0.29

Approved by: MACCARI
 Approval date: 04-feb-2002



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Submission ID: 115029
Sample ID (Request No.): 20013360
User sample ID (lot): 183G403
Sample Date: 18/11/2001
Sample Type: SL010368 (7N1L2E001040) CAPSULE
25MG
Stability Study Start Date: 18/10/2001
Stability Protocol Number: 2001017 - Manufacturer: PD/Pharmacia Nordino
Samples Notes:

Batch Manufacture Date: 17/09/2001
Stability Study: 183G03
Pack Type: 30 ml PLASTIC BOTTLE
Storage Conditions: 25°C/60% UR.
Time Label: 1 MONTH
Preparation purpose: CLINICAL SUPPLY + STABILITY

Condition: **APPROVED**
Status: **COMPLETE**

Method	Controls	Results	M.U.	Spec?	Lower lim	Upper lim	Book-Data Analyses	Analyst	Verifier
013GSC00240 0	CAPSULE APPEARANCE	CONFORMS	bc			14/3/20 NOV 2001	CAPPUCCIO	MACCARI	
	CAPSULE COLOR	CONFORMS	bc			14/3/20 NOV 2001	CAPPUCCIO	MACCARI	
	CONTENT APPEARANCE	CONFORMS	bc			14/3/20 NOV 2001	CAPPUCCIO	MACCARI	
	CONTENT COLOR	CONFORMS	bc			14/3/20 NOV 2001	CAPPUCCIO	MACCARI	
	SMELL	CONFORMS	bc			14/3/20 NOV 2001	CAPPUCCIO	MACCARI	
013GSC011001 S	(HPLC TITER) SAMPLE #1	98.783	%		90.000 - 110.000	14/3/20 NOV 2001	CAPPUCCIO	MACCARI	
	(HPLC TITER) SAMPLE #2	98.218	%		90.000 - 110.000	14/3/20 NOV 2001	CAPPUCCIO	MACCARI	
	(HPLC TITER) SAMPLE #3	98.918	%		90.000 - 110.000	14/3/20 NOV 2001	CAPPUCCIO	MACCARI	
	AVERAGE TITER (HPLC)	98.3	%		90.000 - 110.000	14/3/20 NOV 2001	CAPPUCCIO	MACCARI	
013GSC01100 0	TOTAL CORRELATED SUBSTANCES	0.306	%			14/3/20 NOV 2001	CAPPUCCIO	MACCARI	
	IMPURITIES NOT LESS THAN 0.05% SEE TEXT		%			14/3/20 NOV 2001	CAPPUCCIO	MACCARI	
013GSC011000	(HUMIDITY) SAMPLE #1	1.8	%			14/3/20 NOV 2001	CAPPUCCIO	MACCARI	
	(HUMIDITY) SAMPLE #2	1.6	%			14/3/20 NOV 2001	CAPPUCCIO	MACCARI	
	(HUMIDITY) SAMPLE #3	1.7	%			14/3/20 NOV 2001	CAPPUCCIO	MACCARI	
	AVERAGE HUMIDITY	1.7	%			14/3/20 NOV 2001	CAPPUCCIO	MACCARI	



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Submission No: 115029

Sample ID (Request No.): 20013300

User sample ID (lot): K3G013

Sample Date: 18/11/2001

Sample Type: SU010308 (PNL/281040AD) CAPSULE

25MG

Stability Study Start Date: 18/10/2001

Stability Protocol Number: 2001017 - Manufacturer: PDPharmacia Nordiano

Samples Notes:

Batch Manufacture Date: 17/09/2001

Stability Study: K3G03

Pack Type: 30 ml PLASTIC BOTTLE

Storage Conditions: 25°C/60% U.R.

Time Label: 1 MONTH

Preparation purpose: CLINICAL SUPPLY + STABILITY

Condition: **APPROVED**

Status: **COMPLETE**

Method	Controls	Results	M.U.	Spec?	Lower lim	Upper lim	Book-Data Analyses	Analyst	Verifier
063G0150190 1	(SAMPLE #1)	98.2	%		80.000		14/20 NOV 2001	CAPPUCCHIO	MACCARI
	(SAMPLE #2)	81.8	%		80.000		14/20 NOV 2001	CAPPUCCHIO	MACCARI
	(SAMPLE #3)	92.4	%		80.000		14/20 NOV 2001	CAPPUCCHIO	MACCARI
	(SAMPLE #4)	88.0	%		80.000		14/20 NOV 2001	CAPPUCCHIO	MACCARI
	(SAMPLE #5)	89.0	%		80.000		14/20 NOV 2001	CAPPUCCHIO	MACCARI
	(SAMPLE #6)	94.7	%		80.000		14/20 NOV 2001	CAPPUCCHIO	MACCARI
	(DISSOLUTION)	90.35	%		80.000		14/20 NOV 2001	CAPPUCCHIO	MACCARI
	(STANDARD DEVIATION)	5.25	sd-1				14/20 NOV 2001	CAPPUCCHIO	MACCARI
	(C.V.)	5.81	%				14/20 NOV 2001	CAPPUCCHIO	MACCARI
	(MINIMUM DISSOLUTION VALUE)	81.8	%		80.000		14/20 NOV 2001	CAPPUCCHIO	MACCARI
	(MAXIMUM DISSOLUTION VALUE)	98.24	%		80.000		14/20 NOV 2001	CAPPUCCHIO	MACCARI

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Condition: **APPROVED**

Status: **COMPLETE**

Batch Manufacture Date: 17/02/2001

Stability Study: 03G03

Pack Type: 30 ml PLASTIC BOTTLE

Storage Condition: 25°C/60% U.R.

Time Label: 1 MONTH

Preparation purpose: CLINICAL SUPPLY + STABILITY

Submission No: 115029

Sample ID (Request No.): 200103100

User sample ID (lot): 03G03

Sample Date: 18/11/2001

Sample Type: SU100898 (FNU200040403) CAPSULE

25MG

Stability Study Start Date: 18/10/2001

Stability Protocol Number: 2001017 - Manufacturer: FOPPharmacia Norwano

Samples Notes:

Observations on the Method 083GCO02#00, component: CAPSULE APPEARANCE

Brick red colored capsule containing yellow-orange powder

Observations on the Method 083GSC01#00, component: IMPURITIES NOT LESS THAN 0.05%

Total correlated substances: 0.306%

RRT	Area %
0.06	0.090
1.00	99.60 (SU 11240)
2.15	0.076
2.17	0.140

Approved by: **MACCARI**
Approval date: **30-JAN-2001**



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Submission ID: 115031
Sample ID (Request No.): 20010302
User sample ID (lot): 163G03
Sample Date: 18/11/2001
Sample Type: 8U010888 (PNU02009040) CAPSULE
25MG
Stability Study Start Date: 18/10/2001
Stability Protocol Number: 2001017 - Manufacturer: PDPharmacia Nordano

Batch Manufacture Date: 17/09/2001
Stability Study: 163G03
Pack Type: 30 ml PLASTIC BOTTLE
Storage Conditions: 40°C/75% UR
Time Label: 1 MONTH
Preparation purpose: CLINICAL SUPPLY + STABILITY

Condition: **APPROVED**
Status: **COMPLETE**

Samples Notes:

Method	Controls	Results	M.U.	Spec?	Lower lim	Upper lim	Book-Data Analyses	Analyst	Verifier
063G010240	CAPSULE APPEARANCE	CONFORMS	td			14/3/20 NOV 2001	CAPPUCCHIO	MACCARI	
0	CAPSULE COLOR	CONFORMS	td			14/3/20 NOV 2001	CAPPUCCHIO	MACCARI	
	CONTENT APPEARANCE	CONFORMS	td			14/3/20 NOV 2001	CAPPUCCHIO	MACCARI	
	CONTENT COLOR	CONFORMS	td			14/3/20 NOV 2001	CAPPUCCHIO	MACCARI	
	SMELL	CONFORMS	td			14/3/20 NOV 2001	CAPPUCCHIO	MACCARI	
063G010101	(HPLC TITER) SAMPLE #1	97.43	%		90.000 - 110.000	14/3/20 NOV 2001	CAPPUCCHIO	MACCARI	
S	(HPLC TITER) SAMPLE #2	89.03	%		90.000 - 110.000	14/3/20 NOV 2001	CAPPUCCHIO	MACCARI	
	(HPLC TITER) SAMPLE #3	95.23	%		90.000 - 110.000	14/3/20 NOV 2001	CAPPUCCHIO	MACCARI	
	AVERAGE TITER (HPLC)	97.25	%		90.000 - 110.000	14/3/20 NOV 2001	CAPPUCCHIO	MACCARI	
063G010240	TOTAL CORRELATED SUBSTANCES	0.15	%			14/3/20 NOV 2001	CAPPUCCHIO	MACCARI	
0	IMPURITIES NOT LESS THAN 0.05%	SEE TEXT	%			14/3/20 NOV 2001	CAPPUCCHIO	MACCARI	
063G010100	(HUMIDITY) SAMPLE #1	1.8	%			14/3/20 NOV 2001	CAPPUCCHIO	MACCARI	
	(HUMIDITY) SAMPLE #2	1.9	%			14/3/20 NOV 2001	CAPPUCCHIO	MACCARI	
	(HUMIDITY) SAMPLE #3	1.8	%			14/3/20 NOV 2001	CAPPUCCHIO	MACCARI	
	AVERAGE HUMIDITY	1.83	%			14/3/20 NOV 2001	CAPPUCCHIO	MACCARI	



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Submission Id: 113021
Sample ID (Request No.): 20013302
User sample ID (lot): 1330303
Sample Date: 18/11/2001
Sample Type: SUG10308 (FNU1230040AD) CAPSULE
25MG
Stability Study Start Date: 18/10/2001
Stability Protocol Number: 2001017 - Manufacturer: PDPharmacia Nordisk

Batch Manufacture Date: 17/08/2001
Stability Study: M1303
Pack Type: 30 ml PLASTIC BOTTLE
Storage Conditions: 40°C/75% UR.
Time Label: 1 MONTH
Preparation purpose: CLINICAL SUPPLY + STABILITY

Condition:
APPROVED
Status:
COMPLETE

Samples Notes:

Method	Controls	Results	M.U.	Spec?	Lower lim	Upper lim	Book-Data	Analyses	Analyst	Verifier
0833DS01A0	SAMPLE #1	94.7	%		80.000	143/20 NOV 2001			CAPPUCCHIO	MACCARI
	SAMPLE #2	99.3	%		80.000	143/20 NOV 2001			CAPPUCCHIO	MACCARI
	SAMPLE #3	95.2	%		80.000	143/20 NOV 2001			CAPPUCCHIO	MACCARI
	SAMPLE #4	87.5	%		80.000	143/20 NOV 2001			CAPPUCCHIO	MACCARI
	SAMPLE #5	97.9	%		80.000	143/20 NOV 2001			CAPPUCCHIO	MACCARI
	SAMPLE #6	97.3	%		80.000	143/20 NOV 2001			CAPPUCCHIO	MACCARI
	DISSOLUTION	95.3	%		80.000	143/20 NOV 2001			CAPPUCCHIO	MACCARI
	STANDARD DEVIATION	4.182	std			143/20 NOV 2001			CAPPUCCHIO	MACCARI
	C.V.	4.39	%			143/20 NOV 2001			CAPPUCCHIO	MACCARI
	MINIMUM DISSOLUTION VALUE	87.5	%		80.000	143/20 NOV 2001			CAPPUCCHIO	MACCARI
	MAXIMUM DISSOLUTION VALUE	99.33	%		80.000	143/20 NOV 2001			CAPPUCCHIO	MACCARI



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Reference ID: 119031

Sample ID (Request No.): 20013302

User sample ID (lot): 853G03

Sample Date: 18/11/2001

Sample Type: SJ010305 (PUL2300040)CAPSULE
25MG

Stability Study Start Date: 18/10/2001

Stability Protocol Number: 2001017 - Manufacturer: FIDPharmacia NemoBio

Samples Notes:

Observations on the Method 083GCO02#00, component: CAPSULE APPEARANCE

Brick red colored capsule containing yellow-orange powder

Observations on the Method 083GSC01#00, component: IMPURITIES NOT LESS THAN 0.05%

Total correlated substances: 0.145%

PKRT	Area %
0.68	0.45
1.00	90.65 (SU-11248)
2.17	0.49

Batch Manufacture Date: 17/09/2001

Stability Study: 853G03

Pack Type: 30 ml PLASTIC BOTTLE

Storage Conditions: 40°C/75% UR.

Test Label: 1 MONTH

Preparation purpose: CLINICAL SUPPLY + STABILITY

Condition: **APPROVED**

Status: **COMPLETE**

Approved by: MACCARI
Approval date: 30-nov-2001



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Submission Id: 11406

Sample ID (Request No.): 2001S150

User sample ID (lot): B33303

Sample Date: 01/11/2001

Sample Type: SU010350 (PMU20040AD) CAPSULE

Z5AG

Stability Study Start Date: 18/10/2001

Stability Protocol Number: 2001017 - Manufacture: PO Pharmacia Nordiska

Batch Manufacture Date: 17/08/2001

Stability Study: B33303

Pack Type: BULK

Storage Conditions: TIME ZERO

Time Label: TIME ZERO

Preparation purpose: CLINICAL SUPPLY + STABILITY

Condition:
APPROVED

Status:
COMPLETE

Samples Notes: Opaque brick red colored capsule in containing yellow-orange powder

Method	Controls	Results	M.U.	Spec?	Lower lim	Upper lim	Book-Data Analyses	Analyst	Verifier
0830C001M0 1	APPEARANCE	COMPLIANT	td				14301 OCT 2001	CAPPUCCIO	MACCARI
0830C001M01	HPLC IDENTIFICATION	POSITIVE	td				14301 OCT 2001	CAPPUCCIO	MACCARI
0835T01M01 _R	(HPLC TITER) SAMPLE#1	97.31	%		95.000	103.000	14301 OCT 2001	CAPPUCCIO	MACCARI
	(HPLC TITER) SAMPLE#2	98.10	%		95.000	105.000	14301 OCT 2001	CAPPUCCIO	MACCARI
	(HPLC TITER) SAMPLE#3	98.67	%		95.000	105.000	14301 OCT 2001	CAPPUCCIO	MACCARI
	AVERAGE TITER (HPLC)	98.09	%		95.000	105.000	14301 OCT 2001	CAPPUCCIO	MACCARI
0835S001M0 D	TOTAL CORRELATED SUBSTANCES	0.273	%				14301 OCT 2001	CAPPUCCIO	MACCARI
	IMPURITIES NOT LESS THAN 0.05%	SEE TEXT	%				14301 OCT 2001	CAPPUCCIO	MACCARI
0836K001M00	(HUMIDITY) SAMPLE #1	1.85	%				14301 OCT 2001	CAPPUCCIO	MACCARI
	(HUMIDITY) SAMPLE #2	1.78	%				14301 OCT 2001	CAPPUCCIO	MACCARI
	(HUMIDITY) SAMPLE #3	1.90	%				14301 OCT 2001	CAPPUCCIO	MACCARI
	(HUMIDITY) SAMPLE	1.9	%				14301 OCT 2001	CAPPUCCIO	MACCARI



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Submission ID: 114006
Sample ID (Request No.): 20013158
User sample ID (lot): 183G03
Sample Date: 01/11/2001
Sample Type: SU010358 (P11U2008104D) CAPSULE 25MG

Batch Manufacture Date: 17/02/2001
Stability Study: 183G03
Pack Type: BULK
Storage Condition: TIME ZERO
Time Label: TIME ZERO
Preparation purpose: CLINICAL SUPPLY + STABILITY

Condition: **APPROVED**
Status: **COMPLETE**

Stability Study Start Date: 18/10/2001

Stability Protocol Number: 2001017 - Manufacturer: PO Pharmacia Malaysia

Samples Notes: Opaque brick red colored capsule in containing yellow-orange powder

Method	Controls	Results	M.U.	Spec?	Lower lim	Upper lim	Book-Data Analyses	Analyst	Verifier
083GDS0140 1_12	SAMPLE #1	85.23	%		80.000		14301 OCT 2001	CAPPUCCIO	MAGCARI
	SAMPLE #2	92.79	%		80.000		14301 OCT 2001	CAPPUCCIO	MAGCARI
	SAMPLE #3	98.54	%		80.000		14301 OCT 2001	CAPPUCCIO	MAGCARI
	SAMPLE #4	93.86	%		80.000		14301 OCT 2001	CAPPUCCIO	MAGCARI
	SAMPLE #5	81.52	%		80.000		14301 OCT 2001	CAPPUCCIO	MAGCARI
	SAMPLE #6	84.74	%		80.000		14301 OCT 2001	CAPPUCCIO	MAGCARI
	SAMPLE #7	89.32	%		80.000		14301 OCT 2001	CAPPUCCIO	MAGCARI
	SAMPLE #8	95.91	%		80.000		14301 OCT 2001	CAPPUCCIO	MAGCARI
	SAMPLE #9	90.61	%		80.000		14301 OCT 2001	CAPPUCCIO	MAGCARI
	SAMPLE #10	105.5	%		80.000		14301 OCT 2001	CAPPUCCIO	MAGCARI
	SAMPLE #11	90.31	%		80.000		14301 OCT 2001	CAPPUCCIO	MAGCARI
	SAMPLE #12	83.12	%		80.000		14301 OCT 2001	CAPPUCCIO	MAGCARI
	DISSOLUTION	92.62	%		80.000		14301 OCT 2001	CAPPUCCIO	MAGCARI
	STANDARD DEVIATION	7.031	sd-1				14301 OCT 2001	CAPPUCCIO	MAGCARI
	C.V.	7.59	%				14301 OCT 2001	CAPPUCCIO	MAGCARI
	MINIMUM DISSOLUTION VALUE	81.62	%		80.000		14301 OCT 2001	CAPPUCCIO	MAGCARI
	MAXIMUM DISSOLUTION VALUE	105.5	%		80.000		14301 OCT 2001	CAPPUCCIO	MAGCARI



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Submission #: 114908

Sample ID (Request No.): 20013158

User sample ID (lot): 503503

Sample Date: 01/12/2001

Sample Type: SLU(0000 (PNU200000AD)

CAPSULE

25MG

Stability Study Start Date: 12/10/2001

Stability Product Number: 2001017 - Manufacturer: PD/Pharmacia Nordino

Samples Notes: Opaque brick red colored capsule in containing yellow-orange powder

Batch Manufacture Date: 17/09/2001

Sublot Study: 83503

Pack Type: BULK

Storage Conditions: TIME ZERO

Time Label: TIME ZERO

Preparation purpose: CLINICAL SUPPLY + STABILITY

Condition:
APPROVED

Status:
COMPLETE

Method	Controls	Results	M.U.	Spec?	Lower lim	Upper lim	Book-Data Analyses	Analyst	Verifier
035GMC0140 1	TOTAL AEROBIC BACTERIA	IN LIMITS	td				14301 OCT 2001	CAPPUCCHIO	MACCARI
	ESCHERICHIA COLI	ABSENT	td				14301 OCT 2001	CAPPUCCHIO	MACCARI
	SALMONELLA	ABSENT	td				14301 OCT 2001	CAPPUCCHIO	MACCARI
	FUNGI	IN LIMITS	td				14301 OCT 2001	CAPPUCCHIO	MACCARI
	STAPHYLOCOCCUS AUREUS	ABSENT	td				14301 OCT 2001	CAPPUCCHIO	MACCARI
	ENTEROBACTERIA	IN LIMITS	td				14301 OCT 2001	CAPPUCCHIO	MACCARI



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Submission No: 114806

Sample ID (Request No.): 20013156

User sample ID (Lot): 1835003

Sample Date: 01/11/2001

Sample Type: SL010306 (PRL200940AD)

CAPSULE

25MG

Stability Study Start Date: 18/03/2001

Stability Protocol Number: 2001017 - Manufacturer: FOF Pharmacia Merck

Samples Notes: Opaque brick red colored capsule in containing yellow-orange powder

Batch Manufacture Date: 17/08/2001

Stability Study: 1835003

Pack Type: BULK

Storage Condition: TIME ZERO

Time Label: TIME ZERO

Preparation purpose: CLINICAL SUPPLY + STABILITY

Condition:
APPROVED

Status:
COMPLETE

Method	Controls	Results	M.U.	Spec?	Lower lim	Upper lim	Book-Data Analyses	Analyst	Verifier
0030UC0140	CONTENT UNIFORMITY#1	98.508	%		85.000	- 115.000	143/01 OCT 2001	CAPPUCCO	MACCARI
1	CONTENT UNIFORMITY#2	98.280	%		85.000	- 115.000	143/01 OCT 2001	CAPPUCCO	MACCARI
	CONTENT UNIFORMITY#3	98.928	%		85.000	- 115.000	143/01 OCT 2001	CAPPUCCO	MACCARI
	CONTENT UNIFORMITY#4	97.354	%		85.000	- 115.000	143/01 OCT 2001	CAPPUCCO	MACCARI
	CONTENT UNIFORMITY#5	100.192	%		85.000	- 115.000	143/01 OCT 2001	CAPPUCCO	MACCARI
	CONTENT UNIFORMITY#6	100.479	%		85.000	- 115.000	143/01 OCT 2001	CAPPUCCO	MACCARI
	CONTENT UNIFORMITY#7	101.103	%		85.000	- 115.000	143/01 OCT 2001	CAPPUCCO	MACCARI
	CONTENT UNIFORMITY#8	98.637	%		85.000	- 115.000	143/01 OCT 2001	CAPPUCCO	MACCARI
	CONTENT UNIFORMITY#9	98.947	%		85.000	- 115.000	143/01 OCT 2001	CAPPUCCO	MACCARI
	CONTENT UNIFORMITY#10	100.852	%		85.000	- 115.000	143/01 OCT 2001	CAPPUCCO	MACCARI
	CONTENT UNIFORMITY	99.54	%		85.000	- 115.000	143/01 OCT 2001	CAPPUCCO	MACCARI
	STANDARD DEVIATION	1.192	sd-1				143/01 OCT 2001	CAPPUCCO	MACCARI
	C.V.	1.2	%				143/01 OCT 2001	CAPPUCCO	MACCARI
	CONTENT UNIFORMITY MAX	101.183	%		85.000	- 115.000	143/01 OCT 2001	CAPPUCCO	MACCARI
	CONTENT UNIFORMITY MIN	97.344	%		85.000	- 115.000	143/01 OCT 2001	CAPPUCCO	MACCARI



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Submission No: 114905

Sample ID (Request No.): 20013158

User sample ID (lot): 1P3G03

Sample Date: 01/12/2001

Sample Type: SUJ10358 (PNU230941AD) CAPSULE
250(G)

Stability Study Start Date: 18/07/2001

Stability Protocol Number: 2001017 - Manufacturer: PDMPHarmacia Novartis

Samples Notes: Opaque brick red colored capsule containing yellow-orange powder

Batch Manufacture Date: 17/09/2001

Stability Study: 1P3G03

Pack Type: BULK

Storage Condition: TIME ZERO

Time Label: TIME ZERO

Preparation purpose: CLINICAL SUPPLY + STABILITY

Condition: **APPROVED**

Status: **COMPLETE**

Observations on the Method 083GDS01#_12, component: DISSOLUTION

Dissolution after 15 minutes equal to: 66% (min. 35%-max. 88.7%)

Dissolution after 30 minutes equal to: 92.6% (min. 31.5%-max. 105.6%)

Dissolution after 45 minutes equal to: 97.5% (min. 88%-max. 101.9%)

Observations on the Method 083GMC01#01, component: TOTAL AEROBIC BACTERIA

Total bacterial count < 20 Ufc/g

Observations on the Method 083GMC01#01, component: ENTEROBACTERIA

Enterobacteria < 10 Ufc/g

Observations on the Method 083GMC01#01, component: FUNGI

Fungi (Yeast + Molds) < 10 Ufc/g

Observations on the Method 083GSC01#00, component: IMPURITIES NOT LESS THAN 0.05%

Total correlated substances: 0.273%

RRT	Area %
0.58	0.064
0.91	0.062
1.00	90.727 (SU 11240)
1.06	0.107
2.19	0.060

Observations on the Method 083GTC18#01_IR, component: (HPLC TITER)
SAMPLE #3



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Submission ID: 114805

Sample ID (Request No.): 20073168

User sample ID (lot): 183G03

Sample Date: 01/11/2001

Sample Type: SUB10395 (PIN12009(040)) CAPSULE
25MG

Stability Study Start Date: 18/10/2001

Stability Protocol Number: 2001017 - Manufactures: PDV Pharmacia Nordpho

Batch Manufacture Date: 17/02/2001

Stability Study: 183G03

Pack Type: BULK

Storage Conditions: TIME ZERO

Time Label: TIME ZERO

Preparation purpose: CLINICAL SUPPLY + STABILITY

Condition: **APPROVED**

Status: **COMPLETE**

Samples Notes: Opaque brick red colored capsule containing yellow-orange powder

Observations on the Method 083GTC18#01_IR, component: (HPLC TITER) SAMPLE#3

Observations on the Method 083GTC18#01_IR, component: AVERAGE TITER (HPLC)
Average titer determined based on nine different samples

Approved by: MACCARI
Approval date: 28-Nov-2001